Registration No 524-595 Vol. 1

## ISB'S Front-end PRIA Completeness Screen Draft 3; 10/25/07

EΡΛ	Reccipt Date: 12/22/09	EPA Reg. Number: 5	24-1	202	<u>22</u> 0 7
	Check List Item	Yes	No	N/A	
Ţ	Has the PRIA Fee been Paid; is a cop Pay.gov receipt included in the Submis		~		
2	is an Application Form (EPA Form 8570-1) Included in the Submission Package, is it completely filled out and signed including package type?				::
3	Is a Confidential Statement of Formula (EPA Form 8570-29) included in the Submission Package, is it completely filled out and signed (boxes 1-21)?				
4	Is a Formulator's Exemption Statement (EPA Form 8570-27) Included in the Submission Package?			/	
5	Is a Certification with Respect to Citation of Data (EPA Form 8570-34) Included in the Submission Package?				
6	Is a Data Matrix (EPA Form 8570-35) Included in the Submission Package?				
7	is a Label Included in the Submission Package?			·	
8	Are Data Included in the Submission Package?			/	
9	Is the Submission an Amendment?			V	

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

NOV 2 2 2011

Dr. J. Austin Burns Regulatory Affairs Manager Monsanto Company 800 North Lindbergh Blvd. St. Louis, MO 63137

Subject: MON 89034 x TC1507 x MON 88017 x DAS-59122-7 and MON 89034 x TC1507 x

MON 88017 x DAS-59122-7 RIB Complete™ June 10, 2011 and October 27, 2011

Applications to Amend the Expiration Date for Monsanto SmartStax Products

EPA Registration Nos. 524-581 and 524-595

Dear Dr. Burns:

The amendments referred to above, submitted in connection with registration under Section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, are acceptable subject to the following terms and conditions.

- 1) The expiration date for these products is November 30, 2013.
- 2) The Agency recognizes that large corn rootworm populations, environmental conditions, and protein expression levels can influence corn root damage and may affect the definition of suspected CRW resistance. The Agency plans to work with the registrants to refine the definition of suspected resistance based on these factors. Until such time that the Agency accepts a modified definition of suspected resistance to corn rootworm, resistance will be suspected in cases where the average root damage in the SmartStax field is > 0.5 on the nodal injury scale (NIS) and the frequency of SmartStax with > 0.5 nodes destroyed exceeds 50% of the sampled plants.
- 3) Within 90 days of this amendment, you must submit an enhanced rootworm resistance monitoring plan for SmartStax that accounts for reports of suspected and/or confirmed resistance. The rootworm resistance monitoring plan and the revised definitions for suspected and confirmed resistance for SmartStax must be found acceptable to BPPD by May 1, 2012 and utilized by Monsanto beginning in the 2012 season. This enhanced monitoring program should:

- Be practical and adaptable and provide information on relevant changes in corn rootworm population sensitivity to SmartStax;
- o Be focused on areas where the potential for resistance is greatest for SmartStax and for the corn rootworm active single event components of SmartStax (Cry3Bb1 and Cry34Ab1/Cry35Ab1), based on available information on historical pest pressure, unexpected performance issues, historical suspected and/or confirmed resistance incidents as currently defined or as modified in EPA accepted enhanced monitoring programs, prevailing agronomic practices (e.g. crop rotation versus continuous corn), and academic and extension publications on Bt corn field performance;
- o Involve coordination to the extent possible with other stakeholders, such as academic and extension experts in the states where corn rootworm is a major pest, other registrants of SmartStax, and other registrants of similar products, as appropriate;
- o Be responsive to incidents of suspected or confirmed resistance to the registrant's other products containing the same active ingredient(s), as well as to publicly available reports of suspected or confirmed resistance to other *Bt* protein toxins in SmartStax.
- 4) Within 90 days of this amendment, you must submit an enhanced remedial action plan for SmartStax that includes actions to be taken in response to both suspected and confirmed resistance. This remedial action plan must include a description of steps to be taken in response to customer product performance inquiries and annual reporting to the agency on the outcomes of investigations into any such inquiries that might indicate potential resistance. The program must include revised definitions of unexpected damage to SmartStax corn that could indicate potential suspected resistance. The enhanced remedial action plan must be found acceptable to BPPD by May 1, 2012.
- 5) The Grower Guide or its supplements must include language directing the user to contact a company representative if they observe unexpected insect feeding damage to their SmartStax corn. As part of its follow up on reports of unexpected damage to SmartStax corn, the registrant must determine the nodal injury scale (NIS) of affected corn. If the NIS results fall within the definition of suspected resistance for SmartStax, then until such time as the Agency accepts a modified remedial action plan, the registrant must provide specific guidance to affected growers in managing corn rootworms in the affected fields. This will include 1) providing specific grower guidance to control the adult stage of corn rootworms, where adult beetles are still present and

laying eggs during the season that unexpected damage meets the suspected resistance definition; and 2) where the grower continues to be an existing customer of the registrant or seed company licensee into the following season, providing specific grower guidance and assistance to use an additional or alternative pest control method during the season following the initial finding that unexpected damage meets the suspected resistance definition.

- 6) Monsanto will submit additional modeling, scientific literature, and other scientific information addressing the impact of pyramid PIP use in areas of confirmed resistance to one of the rootworm-active components of the pyramid by August 30, 2012.
- 7) Should resistance to any of the constituent toxins of SmartStax be confirmed (from target pest populations collected in 2012 or prior growing seasons) in accordance with the existing definition of "confirmed resistance" for the appropriate toxin, EPA will reassess and, if EPA concludes it is necessary, Monsanto will revise the refuge/seed blend requirements for SmartStax. The registrants may independently submit updated definitions of confirmed resistance for their respective SmartStax active proteins for EPA's consideration in order to harmonize and/or keep definitions current with scientific standards; any such submission must be found acceptable to BPPD by May 1, 2012. EPA will incorporate all relevant scientific information (including the data required above) in its reassessment of the refuge/seed blend requirements. The revised refuge/seed blend requirements will be effective for the following growing season (after resistance confirmation) in the geographic areas in which resistance was confirmed. The geographic area of confirmed resistance could be less than a single county, a single county, or multiple counties, depending on EPA's analysis of the collected data.
- 8) For the SmartStax block refuge products, submit a revised Compliance Assurance plan by February 28, 2012.

Sincerely.

Keith A. Matthews, Director Biopesticides and Pollution Prevention Division (751 tP)

Enclosure

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

NOV 22 2011

Dr. J. Austin Burns Regulatory Affairs Manager Monsanto Company 800 North Lindbergh Blvd. St. Louis, MO 63137

Subject: MON 89034 x TC1507 x MON 88017 x DAS-59122-7 and MON 89034 x TC1507 x

MON 88017 x DAS-59122-7 RIB Complete™ June 10, 2011 and October 27, 2011 Applications to Amend the Expiration Date for Monsanto SmartStax Products

EPA Registration Nos. 524-581 and 524-595

Dear Dr. Burns:

The amendments referred to above, submitted in connection with registration under Section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, are acceptable subject to the following terms and conditions.

- 1) The expiration date for these products is November 30, 2013.
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## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

- Be practical and adaptable and provide information on relevant changes in corn rootworm population sensitivity to SmartStax;
- o Be focused on areas where the potential for resistance is greatest for SmartStax and for the corn rootworm active single event components of SmartStax (Cry3Bb1and Cry34Ab1/Cry35Ab1), based on available information on historical pest pressure, unexpected performance issues, historical suspected and/or confirmed resistance incidents as currently defined or as modified in EPA accepted enhanced monitoring programs, prevailing agronomic practices (e.g. crop rotation versus continuous corn), and academic and extension publications on Bt corn field performance;
- o Involve coordination to the extent possible with other stakeholders, such as academic and extension experts in the states where corn rootworm is a major pest, other registrants of SmartStax, and other registrants of similar products, as appropriate;
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# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

laying eggs during the season that unexpected damage meets the suspected resistance definition; and 2) where the grower continues to be an existing customer of the registrant or seed company licensee into the following season, providing specific grower guidance and assistance to use an additional or alternative pest control method during the season following the initial finding that unexpected damage meets the suspected resistance definition.

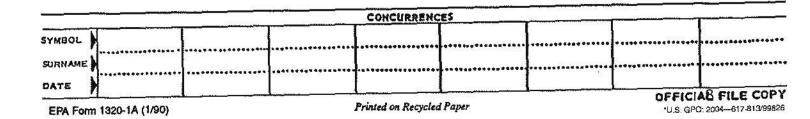
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- 7) Should resistance to any of the constituent toxins of SmartStax be confirmed (from target pest populations collected in 2012 or prior growing seasons) in accordance with the existing definition of "confirmed resistance" for the appropriate toxin. EPA will reassess and, if EPA concludes it is necessary, Monsanto will revise the refuge/seed blend requirements for SmartStax. The registrants may independently submit updated definitions of confirmed resistance for their respective SmartStax active proteins for EPA's consideration in order to harmonize and/or keep definitions current with scientific standards; any such submission must be found acceptable to BPPD by May 1, 2012. EPA will incorporate all relevant scientific information (including the data required above) in its reassessment of the refuge/seed blend requirements. The revised refuge/seed blend requirements will be effective for the following growing season (after resistance confirmation) in the geographic areas in which resistance was confirmed. The geographic area of confirmed resistance could be less than a single county, a single county, or multiple counties, depending on EPA's analysis of the collected data.
- 8) For the SmartStax block refuge products, submit a revised Compliance Assurance plan by February 28, 2012.

Sincerely.

Keith A. Matthews, Director Biopesticides and Pollution

Prevention Division (7511P)

Enclosure



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OCT 27 2011

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Dr. J. Austin Burns Regulatory Affairs Manager Monsanto Company 800 North Lindbergh Blvd. St. Louis, MO 63137

Subject: MON 89034 x TC1507 x MON 88017 x DAS-59122-7 RIB Complete™

June 10, 2011 Application to Amend the Expiration Date

EPA Registration No. 524-595

Dear Dr. Burns:

The amendment referred to above, submitted in connection with registration under Section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable provided that the revised expiration date for this product is November 30, 2011. Per our discussions with Monsanto, the Agency intends to determine a longer term expiration date for this product, along with other SmartStax related products, during the month of November. In order to facilitate this process, please submit a corresponding amendment application.

Sincerely,

Sheryl K.®Reilly, Ph.D. V Chief, Microbial Pesticides Branch

Biopesticides and Pollution Prevention Division (7511P)

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OCT 27 2011

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Dr. J. Austin Bums Regulatory Affairs Manager Monsanto Company 800 North Lindbergh Blvd. St. Louis, MO 63137

Subject: MON 89034 x TC1507 x MON 88017 x DAS-59122-7 RIB Complete™

June 10, 2011 Application to Amend the Expiration Date

EPA Registration No. 524-595

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Sincerely,

Sheryl K. Reilly, Ph.D.

Chief, Microbial Pesticides Branch

Biopesticides and Pollution

Prevention Division (7511P)

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J. Austin Burns Regulatory Affairs Manager (314) 694-6514

October 27, 2011

MONSANTO COMPANY 800 N. LINDBERGH BLVD. ST. LOUIS, MISSOURI 63167 http://www.monsanto.com

Document Processing Desk (PETN)
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7511P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attn: Dr. Sheryl Reilly, Team Leader 92

Subject: Application to extend the registration of MON 89034 × TC1507 × MON 88017 ×

DAS-59122-7 RIB Complete™; EPA Registration Number 524-595; non-PRIA

## Dear Dr. Reilly:

Please find an application for the registration extension of the plant-incorporated protectant MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete Insect Protected, Herbicide-Tolerant Corn (EPA Reg. No. 524-595) enclosed.

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ was conditionally registered on April 8, 2011. The initial time-limited registration expired on October 31, 2011, which was subsequently extended to November 30, 2011 (EPA letter, October 27, 2011).

During the initial registration period, Monsanto, in conjunction with Dow AgroSciences (EPA Reg. No. 68467-16), provided further information supporting this product in accordance with the terms and conditions of registration, including an updated draft label. This current application request is to extend EPA Reg. No. 524-595 for a period of two years beyond the current November, 30, 2011 expiration date based on the EPA's registration decision in the BRAD for this product (EPA Docket ID EPA-HQ-OPP-2011-0362-0002, April 8, 2011; p27). A subsequent registration extension will be requested at that time, based on the revised registration duration scheme for PIP products representing reduced risk for developing insect registration (Optimum® AcreMax<sup>TM</sup> B.t. Corn Seed Blends BRAD; August 4, 2010; p19).

Pursuant to this request, attached is a letter from Dow AgroSciences authorizing data citation related to Events TC1507 and DAS-59122-7.

The documents accompanying this submission are listed in the table below. The table includes the classification categories "A", "B", and "C" for each document, as defined by the Agency:

- Category "A": Materials that can be released to anyone, regardless of affiliation to a foreign or multi-national pesticide producer.
- Category "B": Information can be released only to individuals that attest they are not employees or agents of a foreign or multi-national pesticide producer, as per FIFRA Section 10(g).
- Category "C": Confidential Business Information that is protected from any disclosure indefinitely by provisions put forth by the EPA, as per FIFRA Section 10.

An email containing the fully releasable ("A") documents, with the exception of the data citation authorization letter, is being provided separately.

It is Monsanto's understanding that this request is a non-PRIA action.

• Fee category: Non-PRIA Amendment

• Fee category amount: \$0

Should you require any additional information regarding this application please feel free to contact Daniel Jenkins at 202-383-2851, or myself at 314-694-6514.

Sincerely,

J. Austin Burns, Ph.D.

Regulatory Affairs Manager

Monsanto Company

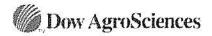
cc: Mike Mendelson, EPA/OPP/BPPD

Dan Jenkins, Monsanto

## Documents accompanying this application

Volume	Category	Document	Hard copy	.pdf file for E-docket
N/A	A	Cover letter	√ √	√
N/A	A	Dow AgroSciences data citation letter	√	
N/A	A	Transmittal document	V	√
1	A	CBI-Deleted version: Administrative Materials for the Application to Amend the Registration of the Plant-Incorporated Protectant, Bacillus thuringiensis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, With an Interspersed In-Field Refuge Configuration Using a Seed Mixture		√
1	В	Administrative Materials for the Application to Amend the Registration of the Plant-Incorporated Protectant, Bacillus thuringiensis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, With an Interspersed In-Field Refuge Configuration Using a Seed Mixture	7	
1	C	Confidential Statement of Formula	<b>√</b>	***************************************

Page 3 of 3,,,,, 13



May 27, 2011

Document Processing Desk Office of Pesticide Programs (7504P) U.S. Environmental Protection Agency Room S-4900, One Potomac Yard 2777 South Crystal Drive Arlington, VA 22202-4501

Attn: Dr. Keith Matthews, Esq., Director Biopesticide and Pollution Prevention Division

#### LETTER AUTHORIZING DATA CITATION

We hereby confirm that Agrigenetics, Inc. d/b/a Mycogen Seeds c/o Dow AgroSciences LLC, on behalf of itself and its affiliates, (collectively, "Dow AgroSciences") authorizes Monsanto Company (Monsanto) to cite, and the U.S. Environmental Protection Agency (EPA) to refer to, data previously submitted by Dow AgroSciences in connection with any of the following products:

- Insect-protected, glufosinate-tolerant maize containing the Cry1F and PAT proteins, Event TC1507 (DAS-01507-1);
- Insect-protected, glufosinate-tolerant maize containing the Cry34/35Ab1 and PAT proteins, Event DAS-59122-7 (DAS-59122-7)

and all relevant data that Dow AgroSciences has provided EPA to support the Section 3 registration extension for MON 89034 x TC1507 x MON 88017 x DAS-59122-7 Insect-Protected, Herbicide-Tolerant Corn (Refuge Advanced™ Powered by SmartStax® / Genuity® SmartStax® RIB Complete™), EPA Registration Nos. 68467-16 and 524-595.

This authorization shall not be construed as authorization to use or consider said data, directly or indirectly, in support of any application submitted by any other applicant, for an application by Monsanto for activities other than the registration request as described herein, or for any other regulatory entity to refer to or rely on this data. Dow AgroSciences does not grant permission for citation or reference of this data for any use not specifically stated herein, does not grant permission for citation or reference of data (including future data) not specified herein, and nothing in this agreement grants permission for the U.S. EPA to provide copies of any data to any party.

If you require further information, please contact the undersigned at 317-337-3692.

Best Regards,

Gregory L. Orr, Ph.D.

Global Regulatory Leader - Corn Traits

Dow AgroSciences LLC

SmartStax\* multi-event technology developed by Dow AgroSciences and Monsonto. \*SmartStax is o registered trademork of Monsanto Technology LLC.



## TRANSMITTAL DOCUMENT

#### SUBMITTED BY

Monsanto Company 800 N. Lindbergh Blvd. St. Louis, MO 63167

# REGULATORY ACTION IN SUPPORT OF WHICH THIS DOCUMENT IS SUBMITTED

Administrative Materials for the Application to Amend the Registration of the Plant-Incorporated Protectant, *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, With an Interspersed In-Field Refuge Configuration Using a Seed Mixture

EPA Registration Number: 524-595

### TRANSMITTAL DATE

October 27, 2011

## MONSANTO REFERENCE No.

11-CR-192E-2R

Page 1 of 2

Monsanto Company

11-CR-192E-2R

15

### LIST OF SUBMITTED DOCUMENTS

## Administrative Materials

Volume 1. Administrative Materials for the Application to Amend the Registration of the Plant-Incorporated Protectant, Bacillus thuringiensis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, With an Interspersed In-Field Refuge Configuration Using a Seed Mixture

MRIE	Number	
Company Official:	J. Austin Burns, Ph.D. Regulatory Affairs Manager (314) 694-6514	/0-27-2011 Date

Company Name: Monsanto Company

Company Contact: Daniel Jenkins, J.D., M.S. U.S. Agency Regulatory Affairs Manager

(202) 383-2851



Monsanto Company

11-CR-192E-2R



### **VOLUME 1**

Administrative Materials for the Application to Amend the Plant-Incorporated Protectant, Bacillus thuringiensis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, With an Interspersed In-Field Refuge Configuration Using a Seed Mixture

EPA Reg. Number: 524-595

### **AUTHORS**

Bradley A. Comstock J. Austin Burns, Ph.D.

### SUBMISSION DATE

October 27, 2011

## SUBMITTING REGISTRANT

Monsanto Company 800 N. Lindbergh Blvd. St. Louis, MO 63167

#### MONSANTO REFERENCE No.

11-CR-192E-2R

Monsanto Company 11-CR-192E-2R Page 1 of 110

The text below applies only to use of the data by the United States Environmental Protection Agency (U.S. EPA) in connection with the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

## STATEMENT OF DATA CONFIDENTIALITY CLAIM

No claim of data confidentiality is being made for information contained in this document on the basis of its falling within the scope of FIFRA §10(d)(1)(A), (B), or (C). However, a supplemental data confidentiality claim is being made for some information claimed herein. The applicable information has been removed to a confidential attachment.

"We submit this material to the United States Environmental Protection Agency specifically under requirements set forth in FIFRA as amended, and consent to use and disclosure of this material by the EPA strictly in accordance with FIFRA. By submitting this material to EPA in accordance with the method and format requirements contained in PR Notice 86-5, we reserve and do not waive any rights involving this material that are or can be claimed by the company notwithstanding this submission to the EPA."

**COMPANY:** 

1

Monsanto Company

COMPANY AGENT:

J. Austin Burns, Ph.D.

Regulatory Affairs Manager

DATE:

October 27, 2011

## GLP COMPLIANCE STATEMENT

The materials in this volume do not meet the requirements of the Good Laboratory Practice Standards, 40 CFR Part 160. This volume provides the administrative materials for the Application to amend the registration of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 Insect Protected, Herbicide-Tolerant Corn with an interspersed in-field refuge configuration using a seed mixture, and therefore were not developed in compliance with 40 CFR Part 160.

Submitter	

J. Austin Burns, Ph.D.

Regulatory Affairs Manager

Sponsor

Jeffrey T. Bookout, M.S., M.B.A. Corn Regulatory Affairs Lead

10-27-11

Date

Study Director

William R. Reeves, Ph.D. Regulatory Affairs Manager

## **VOLUME 1**

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Application to Amend the Registration	n of the Plant-Incorporat	ed Protectant,	Bacillus thuringie					
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J. Austin Burns, Ph.D.	Tel. (314) 694-651		October 27, 2	2011			. , ,	د ا

EPA Form 8570-t (Rev. 3-94) Previous editions are obsolete.

Monsanto Company

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## CONFIDENTIAL STATEMENT OF FORMULA

{CBI Cross Reference Number 1}

1,1222 2,123 2,23 2,1

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## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S. W. WASHINGTON, D.C. 20460

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Certification with I	Respect to Citation o	f Data			
Applicant's/Registrant's Name, Address, and Telephone Number:		EPA Registration Number / File Symbol:			
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis,	MO 63167	524-595			
(314) 694-6514					
Active Ingredient(s) and/or representative test compound(s): Bacil		Date:			
Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1 and Cry35Ab1 Proteins and the Ge		October 27, 2011			
ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Produ × MDN 88017 × DAS-59122-7	October 27, 2011				
General Use Pattern(s) (list all those claimed for this product using 40 0	CFR Part 158:	Product Name:			
Terrestrial field crop		MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete <sup>TM</sup>			
NOTE: If your product is a 100% repackaging of another purchased need to submit this form. You must submit the Formulator's Exemption					
I am responding to a Data-Call-in Notice, and have included w should be used for this purpose).	ith this form a list of companie	s sent offers of compensation (the Data Matrix form			
Section I: METHOD OF DA	TA SUPPORT (Check	one method only)			
I am using the cite-all method of support, and have included w		selective method of support (or cite-all option under			
this form a list of companies sent offers of compensation (the		ethod), and have included with this form a			
Data Matrix Form should be used for this purpose).	used).	of data requirements (the Data Matrix form must be			
Section II: GEN	NERAL OFFER TO PA	AY			
[Required if using the cite-all method or when using the cite-all	option under the selective me	ethod to salisfy one or more data requirements)			
I hereby offer and agree to pay compensation, to other person	s, with regard to the approval	of this application, to the extent required by FIFRA.			
Section III	: CERTIFICATION				
I certify that this application for registration, this form for reregis the application for registration, the form for registration, or the Dala-Call method is indicated in Section 1, this application is supported by all data an identical or substantially similar product, one or more of the ingredient under the data requirements in effect on the date of approval of this application and uses.	l-In response. In addition, if th a in the Agency's files that (t) nts in this product; and (2) is a	e cite-all option or cite-all option under the selective concern the properties or effects of this product or type of data that would be required to be submitted			
I certify that for each exclusive use study cited in support of this registra the wrilten permission of the original dala submilter to cite that study.	tion or reregistration, that I am	n the original data submitter or that I have obtained			
I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and lemms of compensation, if any, to be paid for the use of the study.					
I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registragion? of his product in conformity with FIFRA.					
I certify that the statements I have made on this form and all attacknowingly false of misleading statement may be punishable by fine					
Signature	Data	The death what is a set in the set			
7/	Date	Typed or Princbl Name and Title			
J.an	October 27, 2011	J. Austin Burns, Fh/D.			
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Date: October 27, 2011		ATA MATRIX		EBA Bog No /File Symbol: 53/	1-595 Page 1 of 6
· · · · · · · · · · · · · · · · · · ·		EPA Reg. No./File Symbol: 524-595 Pag Product: MON 89034 × TC1507 ×			
Applicant's/Registrant's Name 8 Monsanto Company, 800 N	Lindbergh Blvd., St. Louis, MO 63167			MON 88017 × DAS-59122	
	rsis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Prot TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identif				HP17662) Necessary for
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Administrative Materials for the Application to Amond the Plant-Incorporated Protectant, Bacillus thuringiensis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, With an Interspersed In-Field Refuge Configuration Using a Seed Mixture		Monsanto Com	pany OWN	Administrative This Submission
NA	Administrative Materials for Dow AgroSciences' and Monsanto's Response to Uncertainties Raised by the SmartStax® RIB Scientific Advisory Panel, Dec 8-9, 2010.	484234-00	Monsanto Com	pany OWN	Administrative Supporting Data
NA	Dow AgroSciences' and Monsanto's Response to Uncertainties Raised by the SmartStax® RIB Scientific Advisory Panel, Dec 8-9, 2010.	484234-01	Monsanto Com	pany OWN	Supporting Data
NA	Monsanto Protocol/Refuge Assurance ('rogram, including Licensee Seed Conditioner's Qualification for Seed Mix Refuge Products (RIB)	48394001	Monsanto Com	pany OWN	Supporting Data
NA	The state of the first state of the first state of the st	N/A	Monsanto Con	pany OWN	Supporting Date
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DATA MATRIX		7////
Date: October 27, 2011	EPA Reg. No./File Symbol: 524-595	Page 2 of 66
Applicant's/Registrant's Name & Address:	Product: MON 89034 × TC1	1507 ×
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	MON 88017 × DAS-59122-7 RIB	Complete <sup>™</sup>

Ingredient Bacillus thuringiensis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7)

Guideline Reference Number Guideline Study Name MRID Number Submitter Status Note Administrative Materials for the Application to Register the Plant-Incorporated Protectant, Bacillus thuringiensis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, With an Interspersed In-Field Refuge Configuration Using a Seed NA Mixture 47943700 Monsanto Company OWN Administrative Five Percent Seed Mix Refuge as an Insect Resistance Management Option for MON 89034 × NA TC1507 × MON 88017 × DAS-59122-7 47943701 Monsanto Company OWN Supporting Data The Benefits of a 5% Interspersed In-field Refage NA Option for SmartStaxTM Corn 47943702 Monsanto Company OWN Benefits Signature Name and Title Date See Page 1 for Signature J. Austin Burns, Ph.D. October 27, 2011 Regulatory Affairs Manager

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	DA	ATA MATRIX		- 3.000	201202
Date: October 27, 2011			E	PA Reg. No./File Symbol: 524-581	Page 3 of 66
Applicant's/Registrant's Name & Monsanto Company, 800 1	Address: N. L'indbergh Blyd., St. Louis, MO 63167			Product: MON 89034 × TC1507 DAS-59122-7	× MON 88017 ×
	msis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, a r their Production in MON 89034 × TC1507 × MON 8801				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Goodwin, B.K., Marra, M.C., and N.E. Piggott. 2009. Farm-Level Benefits of a Refuge Reduction for SmartStax ™. A report from Agri-Analytics, Inc.	n/A	Monsanto Compart	y OWN	Supporting Information
	Burns, J.A. 2009. The Benefits of Refuge Reduction to 5% for SmartSlax Corn	47943702	Monsanto Compan	y OWN	Supporting Information
	Burns, J.A. 2009. Response to U.S. EPA BPPD Letter, Dated March 19, 2009 Regarding Applications to Register MON 89034 ×TC1507 × MON 88017 × DAS-59122-7 EPA File Symbols: 524-LIR (MON); D-395123 (DAS).	n/a	Monsanto Compan	y OWN	Supporting Information
	Bogdanova, N., J.A. Burns, G. Head, et. al. 2009. Condition of Registration for MON 89034 × TC 1507 × MON 88017 × DAS-59122-7 Insect-protected and Herbicide Tolerant Com: Compliance Assurance Plan	47883601	Monsanto Compan	y OWN	Terms and Conditions
	Bogdanova, N., J. Carden, J. Lambert, et. al. 2009. Educational Materials and Information of IRM Requirements Provided by Monsanto Company to Growers of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 Insect-protected and Herbicide Tolerant Com	47883602	Monsanto Compan	y DWN	Terms and Conditions
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D.	Date October 27, 2011	

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DATA MATRIX		64.04.000
Date: October 27, 2011	EPA Reg. No./File Symbol: 524-581	Page 4 of 66
Applicant's/Registrant's Name & Address:	Product: MON 89034 × TC1507 × M	MON 88017 ×
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	DAS-59122-7	

Ingredient Bacillus thuringiensis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMlR245, PHP8999, PV-ZMlR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Head, G., W. Moar, and N. Stozer. 2009. Insect Resistance Monitoring and a Remedial Action Plan for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 Insect-protected and Herbicide Tolerant Cozn	47883603	Monsanto Company	OWN	Terms and Conditions
	Keller, P. 2011. Annual Sales Report for MON 810, MON 863, MON 863 × MON 810, MON 88017, MON 88017 × MON 810, MON 89034, MON 88017 × MON 89034, and MON 88017 × MON 89034 × TC1507 × DAS-59122-7	48367801	Monsanto Crimpany	OWN	Terms and Conditions
	Submission of Pesticide Use Data in Support of the Registrations of MON 810, MON 863, MON 863 × MON 810, MON 88017 × MON 810, MON 89034 × MON 88017, MON 89034 × MON 88017, MON 89034 × TC1507 × MON 88017 × DAS-59122-7	48367800	Monsanto Company	OWN	Terms and Conditions
	Zahora, A. and P. Keller. 2011. 2010 Insect Resistance Management Compliance Assurance Program Report for MDN 89034 × TC1507 × MON 88017 × DAS-59122-7 Insect-protected and Herbicide Tolerant Corn	48367901	Monsanto Company	OWN	1RM
700	Submission of Effreacy Data in Support of the Registration of MDN 89034 × TC1507 × MON 88017 × DAS-59122-7	48369700	Monsanto Company	OWN	Product Characterization
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date October 27, 2011	

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DATA MATRIX		32 35/36/36/3
Date: October 27, 2011	EPA Rcg. No./File Symbol: 524-581	Page 5 of 66
Applicant's/Registrant's Name & Address:	Product: MON 89034 × TC1507 ×	MON 88017 ×
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	DAS-59122-7	

tngredient Bacillus thurtngiensis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7)

Guidelinc Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Head, G., M. Carroll, L. Stork, ct. al. 2011. Com Rootworm Adult Emergence from MON 89034 × TC1507 × MON 88017 × DAS-59122-7, MDN 88017, DAS-59122-7, and Non-Bt Corn with Various Egg Densities in 2010 U.S. Field Trials	48369701	Monsanto Company	OWN	1RM
	Administrative Materials for the Application to Register the Plant-Incorporated Protectant, Bacillus thuringiensis Cry I A. 105, Cry2Ab2, Cry I F, Cry3Bb1, Cry34 and Cry35 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7.		Mousanto Conquany	OWN	Administrative
885,1100	Burns, J.A. 2008. Human Health and Environmental Assessment of the Plant-Incorporated Protectant Bacillus thuringiensis Cry IA. 105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins Produced in the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Monsanto Technical Report MSL0021223.	47444901	Monsanto Company	OWN	Product Characterization
885.1100	Rice, J.F. 2008. Summary of Southern Blot Analyses to Confirm the Presence of MON 89034, TC1507, MON 88017, and DAS-59122-7 in the Combined Trait Corn Product MDN 89034 × TC1507 × MON 88017 × DAS- 59122-7. Monsanto Teclmical Report MSL0021265.	47444902	Monsanio Company	OWN	Product Characterization
885.1100	Taylor, J.P., J.R Groat, and J.D. Masucci. 2007. Southern Blot Analyses to Confirm the Presence of MON 89034 and MON 88017 in the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Monsanto Technical Report MSI.0020682.	47444903	Monsanto Company	own	Product Characterization
Signature	See Page 1 for Signature		Name and Title J. Austin Bunts, Ph.D. Regulatory Affairs Manager	Date October 27, 2011	

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Date: October 27, 2011			E	PA Reg. No./File Symbol: 524-581	Page 6 of 66
Applicant's/Registrant's Name & Monsanto Company, 800 I	Address: N. Lindbergh Blvd., St. Louis, MO 63167			Product: MON 89034 × TC150 DAS-59122-7	
	ensis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, a r their Production in MON 89034 × TC1507 × MON 8801				
Guideline Reference Number	Guidelinc Study Name	MRID Number	Submitter	Status	Note
885,1100	Schafer, B.W., C.Q. Cía, and S.K. Embrey. 2008. Southern Blot Analyses to Confirm the Presence of TC1507 and DAS-59122-7 in the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Dow AgroSciences Study 1D 071179.	47444904	Monsanio Compan	y OWN	Product Characterization
885.1100	Murphy, J.A. and J.S. McClain. 2008. Summary of Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, CP4 EPSPS, Cry34Ab1, Cry35Ab1 and PAT Protein Levels in the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7 Produced in US Field Trials in 2006. Monsanto Technical Report MSL0021266.	47444905	Monsanto Compani	y OWN	Product Characterization
885.1100	Stillwell, L. and A. Silvanovich. 2007. Assessment of Cryl A.105, Cry2Ab2, Cry3Bb1, and CP4 EPSPS Protein Levels in the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Monsanto Technical Report MSL0021070.	47444906	Monsanto Compan	v OWN	Production Characterization
885.1100	Phillips, A.M. 2008. Cry34Ab1, Cry35Ab1, Cry1F, and PAT Protein Levels in Hybrid Maize TC1507, DAS-59122-7, MON 89034 × TC1507 × MON 88017 × DAS-59122-7, and a Conventional Control from the Monsanto 2006 Production Plan 06-01-52-04. Dow AgroSciences Study ID 061026.06.	47444907	Monsanto Compan		Product Characterization
N/A	Levine, S. 2008. Studies Performed to Evaluate the Potential for Interactions among Cry Proteins Produced by MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Monsanto Technical Report MSL0021267.	47444908	Monsanto Compan		Environmental Assessment
Signature	See Page 1 for Signature	\ \frac{1}{2} \tag{1}	Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Mana	Date October 27, 2011	

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DATA MATRIX	
Date: October 27, 2011	EPA Reg. No./File Symbol: 524-581 Page 7 of 66
Applicant's/Registrant's Name & Address:	Product: MON 89034 × TC1507 × MON 88017 ×
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	DAS-59122-7

Ingredient Bacillus thuringiensis Cry IA.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Irlentifier: MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	MacRae, T. 2008. Evaluation of Potential for Interaction Between the <i>Bacillus thuringiensis</i> Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins. Monsanto Technical Report MSL0020554.	47444909	Monsanto Company	OWN	Environmental Assessment
N/A	Levine, S. 2008. Evaluation of the Potential for Interactions among Cry Proteins Produced by MON 89034 × TC1507 × MON 88017 × DAS-59122-7 by Insect Bioassay. Monsanto Technical Report MSL0021104.	47444910	Monsanto Conipany	OWN	Environmental Assessment
N/A	Head, G. and N. Storer. 2008. Insect Resistance Management Plan for MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Monsanto Technical Report MSL0021285.	47444911	Monsanto Company	OWN	1RM
N/A	Levine, S. and J. Huesing. 2008. Endangered Species Impact Assessment for the Cumbined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Monsanto Technical Report MSL0021268.	47444912	Monsanto Company	OWN	Environntental Assessment
885,4340	Paradise, M. 2008. Evaluation of Potential Dictary Effects of Pollen From the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7 on the Ladybird Beetle Coleomegillo moculata (Culenptera: Coccinellidae). Mnnsanto Technical Report MSL 0021036.	47444913	Monsan'o Company	own	Environmental Assessment
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date October 27, 2011	

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	N. Lindbergh Blvd., St. Louis, MO 63167			Product: MON 89034	
Ingredient Bacillus thuring Identifier: MON-89@34-3)	iensis Cry1A.105 and Cry2Ab2 Proteins and the Genelic i	Material (Vector PV	-ZMIR245) Necessary fo	r their Production in MON 89034 (Of	ECD Unique
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Updated Compliance Assurance Plan, Educational Materials, IRM Monitoring, and a Remedial Action Plan for MON 89034 (EPA Reg. No 524-575) and MON 89034 × MON 88tl17 (EPA Reg. No. 524-57ft) Insect-Protected and Herbicide-Tolerant Corn	483696-01	Monsanto Comp	pany OWN	Terms & Conditions
	Annual Sales Report for MON 810, MON 863, MON 863 × MON 810, MON 88017, MON 88017 × MON 810, MON 89034, MON 88017 × MON 89034, and MON 88017 × MDN 89034 × TC1507 × DAS-59122-7 (EPA Reg. Nos. 524-489, 524-528, 524-545, 524-551, 524-552, 524-575, 524-576, and 524-581)	483678-01	Monsanto Comp	oany OWN	Terms & Conditions
	Enhanced Insect Resistance Management Compliance Assurance Program for Com Borer Protected Bt Corn, Corn Rootworm-Protected Bt Corn, and Corn Borer / Corn Rootworm Protected Stacked Bt Corn.	483751-01	ABSTC	OWN	Terms & Conditions
	Baseline Assessment of Bt Susceptibility of Corn Earworm, <i>Helicaverpa zea</i> , to Cry1 A 105; 2009 Collections and Assays (Lang, B. 2010)	48207401	Monsanto Comp	Dany OWN	IRM- Condition of Registration
	Baseline Susceptibility of the European Corn Borer, Ostrinia mubilasis, to Cry1A.105 and Cry2Ab2 Bt Proteins (Siegfried, B. and Spencer, T. 2010)	48207402	Monsanto Com	pany OWN	IRM- Condition of Registration
	2010 Insect Resistance Management Compliance Assurance Program Report for Corn Borer Protected Bt Corn MON 89034 (EPA Reg. No. 524-575)		Monsauto Com	pany OWN	IRM- Condition of Registration
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Ma		

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Date: October 27, 2011		ATA MATRIX		CDA Dug No (	File Symbol: 524-575	Page 9 of 66
Applicant's/Registrant's Name &	Address: N. Lindbergh Blvd., St. Louis, MO 63167			Product: MC		Tage 7 of oo
	rensis Cryt A. 105 and Cry2 Ab2 Proteins and the Genetic N	Material (Vector PV	/-ZMIR245) Necessary fo			CD Unique
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter		Status	Note
	Baseline Susceptibility of Southwestern Corn Borer, Diarraca grandiosella, to Cryl A. 105 and Cry2 Ab2 Bt Proteins (Song, Q., Sun, Y. and Wang, Q. 2009)	48207403	Monsanto Com	pany	OWN	IRM- Condition of Registration
	Annual Sales report for MON 810 (EPA Reg.No. 524- 489], MON 863 (EPA Reg. No. 524-528), MON 863 x MON 810 (EPA Reg. No. 524-545), MON 88017 (EPA Reg. No. 524-551), MON 89034 (EPA Reg. No. 524-575) and MON 89034 x MON 88107 (EPA Reg. No. 524-576)	479614-01	Monsanto Com	pany	own	Terms & Conditions
	Updated Compliance Assurance Plan, Educational Materials, tRM Monitoring, and a Remedial Action Plan for MON 89034 and MON 89034× MON 88017 Insect- Protected and Herbicide-Tolerant Com (Keller, P. 2011)	479033501	Monsanto Com	pany	own	Conditions of Registration
	Supplemental Information for MRID No. 46951402 "Amended Report for MSL-20072: Molecular analysis of Com MON 89034".	471275-03	Munsanto Com	pany	OWN	Product Characterization
	Supplemental Information for MRID No. 46951403 "Assessment of the Cryt A. 105 and Cry2Ab2 Protein Levels in Tissues of Insect-Protected Corn MON 89034 Produced in 2005 U.S. Field Trials".	471275-05	Monsanto Com	pany	_ own	Product Characterization
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regurlatory Affairs Ma		Date October 27, 2011	

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	N. Lindbergh Blvd., St. Louis, MO 63167			Product: MON 89034	
Ingredient Bacillus thuring Identifier: MON-89Ø34-3)	riensis CryIA.105 and Cry2Ab2 Proteins and the Genetic N	Aaterial (Veclor PV	-ZM1R245) Necessary for	their Production in MON 89034 (O	ECD Unique
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
<b>\$</b> 85,1100	Bogdanova, N.N. 2006. Human Health and Environmental Assessment of the Plant-Incorporated Protectant Bacillus fluringiensis Cryl A.105 and Cry2Ab2 Proteins Produced in Com MON 89034.	469514-01	Monsanto Compa	iny OWN	Product Characterizatinn
885.1100	Rice, J.F., B.J. Wolff, J.R., Groat, N.K. Scanton, J.C. Jemings, and J.D. Masucci. 2006. Amended Report for MSL-20072; Molecular Analysis of Corn MON \$9034. Monsanto Technical Report MSL-20311.	469514-02	Monsanto Compa	my OWN	Product Characterization
885.1100	Hartmann, A.J., K.E. Niemcyer, and A. Silvanovich. 2006. Assessment of the Cryt A.105 and Cry2Ab2 Protein Levels in Tissues of Insect-Protected Corn MON 89034 Produced in 2005 U.S. Field Trials. Monsanto Technical Report MSL-20285.	469514-03	Monsanto Compa	my OWN	Product Characterization
885.1100	Karunanandaa, K., J.J. Thorp, M.E. Goley, S.L. Levine, and A. Silvanovich. 2006. Characterization of the Cry2Ab2 Protein Purified from the Corn Grain of MON 89034 and Comparison of the Physicochemical and Functional Properties of the Plant-Produced and E. coli-Produced Cry2Ab2 Proteins. Monsanto Technical Report MSL-20071.	469514-04	Monsanto Compa	my OWN	Product Characterization
Signalure	See Page 1 for Signature		Name and Tale J. Auslin Burns, Ph.D. Regulatory Affairs Man	Date October 27, 2011	

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.(100	Levine, S.L. and J. Uffman. 2006. Evaluation of the Functional Equivalence of the Cry2Ab2 Protein Produced in E.Coli and Bt Against a Sensitive Lepidopteran Species. Mousanto Technical Report MSL-20132.	469514-05	Monsanto Compa	ny OWN	Product Characterization
885.(100	Rice, J.F., B.J. Wolff, J.C. Jennings, and J.D. Masucci. 2005. Summary of Southern Blot Analysis of MON 89034 and MON 89597 Corn. Monsanto Technical Report MSL-20068	466945-01	Monsanto Compa	ny OWN	Product Characterization
885.1100	Goertz, B., T. Ganguly, J. Lee, T. Lee, and E.A. Rice. 2005. Characterization of the Cryta. 105 (Protein Purified from the Corn Grain of MON 89034 and Comparison of the Physicochemical and Functional Properties of the Plant-Produced and E.coli-Produced Cryta. 105 Proteins. Monsanto Technical Report MSf. 19960.	466946-04	Monsanto Compa	ny OWN	Product Characterization
	Supplemental Information for MRfD No. 46951402 "Amended Report for MSL-20072; Molecular analysis of Com MON 89034".	47(275-03	Monsanto Compa	ny OWN	Product Characterization
	Supplemental Information for MRID No. 4695 (403) "Assessment of the CryLA 105 and Cry2Ab2 Protein Levels in Tissues of Insect-Protected Corn MON 89034 Produced in 2005 U.S. Field Trials".	47 (275-05	Monsanto Compa	nyOWN	Product Characterization
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	N. Lindbergh Blvd., St. Louis, MO 63167			Product: MON 89034	
Ingredient Bacillus (huring) Identifier: MON-89034-3)	iensis Cry1A.105 and Cry2Ab2 Proteins and the Genetic N	/laterial (Vcctor PV	-ZMIR245) Necessary for	r their Production in MON 89034 (C	DECD Unique
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.tt00	Bogdanova, N.N. 2005. Structurat and Functional Similarity of the Cryt A. 105 Protein to Cryt A Class of Bactilus thuringtensis Proteins. Monsanto Technicat Report 05-RA-62-01.	466946-01	Monsanto Comp	nany OWN	Product Characterization
860.1340	Dudin, Y.A and P. Chinnadurai. 2005. Qualitative Detection Method for the Cry2Ab2 Protein in Corn Leaf and Seed of MON 89034 and MON 89597. Monsanto Technical Report 05-RA-39-04.	466945-03	Monsantn Cump	pany OWN	Product Characterization
885.3050	Bonnette, K.L. 2006. An acute oral toxicity study in mice with Cry2Ab2 protein. Monsanto Study CRO-2005-049.	4695†4-06	Monsanto Comp	oany OWN	Huntan Health Assessment
885.1100	Kapadia, S.A. and E.A. Rice. 2006. Assessment of the m vino Digestibility of the Cry2Ab2 Protein in Simulated Gastric Fluid. Monsanto Technical Report MSL-19931.	469514-07	Monsanto Comp	oany OWN	Human Health Assessment
885.It00	Kapadia, S. and E.A. Rice. 2005. Assessment of the In witro Digestibility of the CrytA. 105 Protein in Simulated Intestinal Fluid. Monsanto Technical Report MSL-19930.	469514-08	Monsanto Comp	oany OWN	Human Health Assessment
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	N. Lindbergh Blvd., St. Louis, MO 63167	Product. MON 89034			
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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Nore
885.1100	MeCoy, R.L. and A. Silvanovich. 2005. Bioinformatics Analysis of the Cry1A. 105 Protein Utilizing the AD5, TOXIN5, and ALLPEPTIDES Databases. Monsanto Technical Report MSL-19686.	466946-05	Monsanto Comp	any OWN	Human Health Assessment
885.1100	Thorp, J.J. and M.E. Goley. 2006. Assessment of the in vitro Digestibility of the Cry2Ab2 Protein in Simulated Intestinal Fluid. Morsanto Technical Report MSL-19938	469514-09	Monsanio Coilip	any OWN	Human Health Assessment
885.1100	McClain, J.S. and A. Silvanovich. 2006. Bioinformatics Evaluation of the Cryl A. 105 Protein Utilizing the AD6, TOXIN5, and ALLPEPTIDES Databases. Monsanto Technical Report MSL-20351.	469514-10	Monsante Comp	any OWN	Human Health Assessinent
885.1100	Kapadia, S.A. and E.A. Rice. 2005. Assessment of the in vitro Digestibility of the Cryl A. 105 Protein in Simulated Gastrie Fluid. Monsanto Technical Report MSL-19929.	466946-06	Monsanto Comp.	any OWN	Human Health Assessment
885.1100	Goley, M.E. and J.J. Thorp. 2005. Immunodetection of Cry2Ab2 and Cry1A.105 Proteins in Corn Grain from MON 89034 Following Heat Treatment. Monsanto Technical Report MSL-19899.	466946-07	Monsanto Company DWN		Human Health Assessment
885.3050	Bonnette, K.L. 2005. An Acute Oral Toxicity Study in Mice with Cry1A.105 Prolein. Monsanto Study CRO-2005-050.	466946-03	Monsanto Comp	any OWN	Human Health Assessment
Signature See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Mai	Date October 27, 2011		

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Applicants/Registrants Name & Monsanto Company, 800	Address: N. Lindbergh Blvd., St. Louis, MO 63167	50000 00000		Product: 1	MON 89034	
Ingredient Bacillus thuring Identifier: MON-89@34-3)	iensis Cry1A.105 and Cry2Ab2 Proteins and the Genetic N	laterial (Vector PV	-ZMIR245) Necessary fo	or their Produ	ection in MON 89034 (OE	CD Unique
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter		Status	Note
885.1100	McClain, J.S. and A. Silvanovich. 2006. Bioinformatics Analysis of the Cry2Ab2 Protein Utilizing the AD6, TOXIN5, and ALLPEPTIDES Databases. Monsanto Technical Report MSL-20307.	469514-11	Mansanto Com	pany	own	Human Health Assessment
885.4050	Davis, S.W. 2006. Comparison of Broiler Performance and Careass Parameters When Fed Diets Containing MON 89034, Control or Commercial Corn. Monsanto Study 05-01-50-13, Amended Report.	469514-12	Monsanto Com	pany	OWN	Human Health Assessment
N/A	MacRae, T.C., C.R. Brown, and S.L. Levine. 2006. Spectrum of Insecticidal Activity of Bacillus thuringiensis Cry1A.105 Protein. Monsanto Technical Report MSL- 20230.	469514-13	Monsanto Com	pany	О₩И	Environmental Assessment
N/A	MacRac, T.C., C.R. Brown, and S.L. Levine. 2006. Spectrum of Insecticidal Activity of Bacillus thuringiensis Cry2Ab2 Protein. Monsanto Technical Report MSL- 20229.	4695 [4-14	Monsanto Com	pany	OWN	Environmental Assessment
N/A	Headrick, J.M., O. Heredia, I.O. Oyediran, and T.T. Vaughn. 2006. Assessment of the Efficacy of Lepid opteran-protected Corn MON 89034 and MON 89597 Against Major Insect Pests in United States, Puerto Rico and Argentina During 2003-2004 Seasons. Monsanto Technical Report 05-RA-39-05.	469514-15	Monsanto Com		OWN	Environmental Assessment
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D Regulatory Affairs M		Date October 27, 2011	

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Teixeira, D. 2006. Evaluation of Dietary Effects of Lyophilized Leaf Tissue from Corn MON 89034 in a Chronic Exposure Study with Collembola (Folsomia condida). Monsanto Technical Report MSL-20169.	469514-16	Monsante Company	OWN	Eovironmental Assessment
885.4340	Palmer, S.J. and H.O. Krueger. 2006. Evaluation of Exposure to MON 89034 with the Cladocerao Daphata magna: An acute static-renewal test with corn pollen. Monsanto Study WL-2005-011.	469514-17	Monsanio Company	OWN	Environmental Assessment
885.6200	Sindermann, A.B., J.R. Porch, and H.O. Krueger. 2006. Evaluation of Potential Effects of Exposure to Cry1A.105 Protein in an Acute Study with the Earthworm in an Artificial Soil Substrate. Minisanto Technical Report MSL-20147.	469514-18	Monsanio Company	OWN	Environmental Assessment
885.4380	Richards, K.B. 2006. Evaluation of the Dictary Effect(s) of a Cryl A. 105 Protein on Honeybec Larvae (Apis mellifera L.). Monsanto Study CA-2005-071.	469514-19	Monsanto Company	OWN	Environmental Assessment
885.4380	Richards, K.B. 2006. Evaluation of the Dictary Effect(s) of a Cry I A.105 Protein on Adult Honeybees (Apis mellifera L.). Monsanto Study CA-2005-072	469514-20	Monsanto Company	OWN	Environmental Assessment
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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Paradise, M.S. 2006. Evaluation of Potential Dietary Effects of Cry1A.105 Protein on the Ladybird Beetle, Coleomegilla inaculata (Coleoptera: Coccinellidae). Monsanto Technical Report MSL-20150.	469514-21	Monsanto Company	OWN	Environmental Assessment
885.4340	Paradise, M.S. 2006. Evaluation of Potential Dietary Effects of Cry2Ab2 Protein on the Ladybird Beetle, Coleomegilla maculata (Coleoptera: Coccinellidae). Monsanto Technical Report MSL-20151.	469514-22	Monsanto Company	own	Environmental Assessment
885.4340	Teixeira, D. 2006. Evaluation of Potential Dietary Effects of Cryl A. 105 Protein on Minute Pirate Bugs, Orius insidiosus (Hemiptera: Anthoeoridae). Monsanio Technical Report MSL-20170.	469514-23	Monsanio Company	OWN	Environmental Assessment
885.4340	Teixeira, D. 2006. Evaluation of Potential Dietary Effects of Cry2Ab2 Protein on Minute Pirate Bugs, Orius tnsidiosus (Hemiptera: Anthocoridae). Monsanto Technical Report MSL-20171.	469514-24	Monsanto Company	OWN	Environmental Assessment
885.4340	Sindermann, A.B., J.R. Porelt, and H.O. Krueger. 2006. Evaluation of Potential Effects of Exposure to Cry1A.105 Protein in an Acute Study with the Parasitic Wasp, <i>Ichneumon promissorius</i> (Hymenoptera: Ichneumonidae). Monsanto Technical Report MSL-20149.	469514-25	Monsanio Company	OWN	Environmental Assessment
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manag	Date October 27, 2011	

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4050	Gallagher, S.P. and J.B. Beavers. 2006. Evaluation of Potential Dietary Effects of MON 89034 with the Northern Bobwhite: an Eight-day Dietary Study with Corn Grain. Monsanto Technical Report WŁ-2005-012.	469514-27	Monsanto Company	own	Environmental Assessment
885.5200	Mucth, M., T. Curran, J. Warren, S. Dubelman, M. Glaspie, J. Murphy, S. Levine, J. Holtmeyer, and C. Jiang. 2006. Aerobic Soil Degradation of the Purified Cry2Ab2 and Cry1A.105 Proteins. Monsanto Technical Report MSL-20174.	4695 <b>14-28</b>	Monsanio Company	OWN	Environmental Assessment
N/A	Huesing, J.E., J.J. Duan, and S.L. Levine. 2006. Endangered Species Risk Assessment for Corn MON 89034. Monsanto Technical Report MSL0020394.	469514-29	Monsanio Company	OWN	Environmental Assessment
N/A	MacRae, T.C., C.R. Brown, S.L. Levine. 2005. Evaluation of the Potential for Interactions Between the Bacillus thuringtensis Proteins Cry [A. 105 and Cry2Ab2. Monsanto Technical Report MSL-19859.	466946-02	Monsanto Company	OWN	Environmental Assessment
885.4340	Sindenmann, A.B., J.R. Porch, and H.O. Krueger. 2006. Evaluation of Potential Effects of Exposure to Cry2Ab2 Protein in an Acute Study with the Parasitic Wasp, Ichneumon promissorius (Hymenoptera: Ichneumonidae). Monsanto Technical Report MSL-20148.	469514-26	Monsanto Company	OWN	Environmental Assessment
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date October 27, 2011	

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	D/	ATA MATRIX			20174219
Date: October 27, 2011			ļ.,	EPA Reg. No. File Symbol: 524-575	Page 18 of 66
Applicant's/Registrant's Name & Monsanto Company, 800	Address: N. Lindbergh Blvd., St. Louis, MO 63167	and the state of t		Product: MON 89034	
ngredient Bacillus thuring dentifier: MON-89Ø34-3)	giensis Cry1A.105 and Cry2Ab2 Proteins and the Genetic	Materiol (Vector PV	V-ZMIR245) Necessary for	their Production in MON 89034 (O	ECD Unique
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Palmer, S.J. and H.O. Krueger. 2000. Insect Protection Protein 2: An Acute Toxicity Study With the Earthworm in an Antificial Soil Substrate. Monsanto Technical Report MSL-16177	450863-13	Monsanto Compa	ny OWN	Environmental Assessment
885.4380	Maggi, V.L. 2000. Evaluation of dictary effect(s) of purified Boctilus thuringiensis Cry2Ab2 protein on honey bee larvae. Monsanto Technical Report MSL-16961.	453371-02	Monsanto Compa	ny OWN	Environmental Assessment
885.4340	Teixeira, D. 2000. Assessment of Chronic Toxicity of Cotton Tissue Containing Insect Protection Protein 2 to Collembola (Folsomia candido), Amended report.  Monsanto Technical Report MSL-16174.	450863-14	Monsanio Compa		Environmental Assessment
885.4340	Palmer, S. and H. Krueger. 2000. Insect Protection Protein 2: A Dictary Toxicity Study with Parasitic Hymenoptera ( <i>Nasonia vitripennis</i> ). Monsanto Technical Repon MSL-16173.	450863-10	Monsanto Compa	iny OWN	Environmental Assessment
885.4380	Maggi, V.L. 2000. Evaluation of the Dietary Effect(s) of Insect Protection Protein 2 on Adult Honey Bees (Apis mellifera L.). Monsanto Technical Repon MSL-16176.	450863-08	Monsanio Compa	iny OWN	Environmental Assessment
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Man	Date October 27, 2011	

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	DA	TA MATRIX			
Date: October 27, 2011				EPA Reg. No./File Symbol: 524-575	Page 19 of 66
	Address: N. Lindbergh Blvd., St. Louis, MO 63167  glensis Cryl A. 105 and Cry2 Ab2 Proteins and the Genetic I	Material (Vector P)		Product: MON 89034 their Production in MON 89034 (OE	CD Unique
Identifier: MON-89Ø34-3) Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	Head, G. 2006. Insect Resistance Management Plan for Second Generation Lepidopteran-Protected Corn, MDN 89034. Monsanto Technical Report 06-RA-39-06.	469514-30	Monsanto Compa		IRM
	Bogdanova, N. and A. Crawford (2007). Public Interest Document Supporting Registration of Bactitus thuringiensis Cry I A. 105, Cry2 Ab2 and Cry3 Bb I Proteins in Insect-Protected Corn MON 89034 and MON 89034 x MON 88017	472797-01	Monsanto Compa	ny OWN	Benefits
	Bogdanova, N., S. Dubelman, M. Mueth, J. Murphy and A. Silvanovich (2007). Responses to EPA Questions Regarding Application 524-LTL to register Insect- Protected Corn MON 89034 (MRID 46951428)	471403-01	Monsanto Compa	iny DWN	Misc.
	Bogdanova, N., (2007) Responses to EPA Questions Regarding Applications 524-LTL and 524-LTL to Register trisect-Protected Corn MDN 89034 and MON 89034 x MDN 88017 (MRtD 46951400 and 46951300)	471275-01	Monsanto Compa	iny OWN	Misc.
	Bogdanova, N, (2007). Supplemental Information to Address EPA Questions Regarding Applications 524-LTL and 524-LTL Io Register threet-Protected Corn MON 89034 and MON 89034 x MON 88017 (MRtD 46951400 and 46951300)	470794-02	Monsanto Compa	iny OWN	Misc.
Signature See Page 1 for Signature		Name attd Title J. Austin Burns, Ph.D. Regulatory Atfairs Man	Date October 27, 2011		

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	D/	ATA MATRIX			
Date: October 27, 2011				EPA Reg. No./File Symbol: 68467-2	Page 20 of 6
Applicant's/Registrant's Name & Monsanto Company, 800 ]	Address: N. Lindbergh Blvd., St. Louis, MO 63167	, P		Product: Herculex® I Insect Pro	lection
Ingredient B.t. Cry1F prote	ein and the genetic material necessary for production (plass	mid insert PHP8999	)) in maize (OECD Identi	fier: DAS-Ø15Ø7-1)	
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Acute oral toxicity in mice: Cry IF Bacullus thuringiensis subsp. aizawai delta endotoxin	44691101	68467	PER	
	Effectiveness data for <i>Bacillus tlinninglensis</i> var, aizawai CrytF insect control protein as expressed in maize	44691102	68467	PER	
	Background document on resistance management	44691103	68467	PER	
	Product Characterization Data for Bacillus thuringiensis var. aizawai Cry IF Insect Control Protein as expressed in Maize	44714801	68467	PER	
	Characterization of Gene Inserts-Bacillus thuringiensis var. aizawai Cry1F Insect Control Proteins Expressed in Maize	44714802	68467	PER	
	Equivalency of Microbial and Maize Expressed Cry1F Protein; Characterization of Test Substances for Biochemical and Toxicological Studies. In Vitro Digestibility of Microbial and Maize Expressed Cry1F Protein Under Simulated Gastric Conditions	44714803	68467	PER	
Signature See Page 1 for Signature		Nante and Title J. Austin Burns, Ph.D. Regulatory Atlairs Ma		20000	

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	D/	ATA MATRIX			
Date: October 27, 2011		200		EPA Reg. No./File Symbol: 68467-2	Page 21 of 66
Applicant's/Registrant's Name & Monsanto Company, 800 I	Address: N. Lindbergh Blvd., St. Louis, MO 63167			Product: Herculex® I Insect Prote	ection
Ingredient B.t. Cry1F prote	ein and the genetic material necessary for production (plas	mid insert PHP8999	9) in maize (OECD Identi	fier: DAS-Øt5Ø7-1)	
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Quantitative ELISA Analysis of Cry1F Expression levels in Maize MPS Inbred Lines 1360, 1365, 1366, and 1369. (Interim Report)	44714804	68467	PER	
	Comparison of Amino Acid Sequence Similarity of Cry IF and PAT Proteins to Known Allergen Protein	44971701	68467	PER	
	Microbial B.t. Cry1F (truncated) Delta-Endotoxin: Maize-Inscet-Pest Susceptibility Study	45020101	68467	PER	
	Characterization of inserted genes in Cry1F maize line 1507	45020102	68467	PER	
	Effectiveness Data for Bacillus thuringieusis var. aizawai Cryff Insect Control Protein as Expressed in Maize	44691102	68467	PER	
	Characterization of Expressed Cry1F Protein in Maize Tissues (Pollen, Grain, Grain-Containing Feed, and Purified Maize-Expressed Cry1F Protein) and Microbial Expressed Cry1F Delta Endotoxin by Biological and Biochemical Procedures	45020103	68467	PER	
	Quantitative ELtSA Analysis of Cry1F and PAT Expression levels to and Compositional Analysis of Maize Inbred and Hybrid Lines 1362 and 1507	45020104	68467	PER	
Signature	See Page 1 for Signature		Name and Title J. Austin Bums, Ph.D. Regulatory Affairs Ma		

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401 M Street, S.W., Washingto	on, DC 20460. Do not send the form to this address.			<u> </u>	
	DA	ATA MATRIX			
Date: October 27, 2011 Applicant's/Registrant's Name &	Addraga		E	PA Reg. No.fFile Symbol: 68467-2	Page 22 of 66
Monsanto Company, 800 I	N. Lindbergh Blvd., St. Louis, MO 63167 in and the genetic material necessary for production plasm	id incort PUD9000		roduct: Herculex® I Insect Prot	ection
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Environmental Fate of Cry1F Protein incorporated into Soil	45020105	68467	PER	
	Cry IF Bacillus thuringiensis var. aizawai Delta Endotoxin: An Acute Toxicity Study with the Earthworm in an Articial Soil Substrate	45020106	68467	PER	
	Chronic exposure of Folsomia candida to bacterially expressed Cryl F protein	45020107	68467	PER	
OECD 202	B.r. Cry tF delta endotoxin: A 48-hour static-renewal acute toxicity test with the Cladoceran (Daplinia magna) using bacterially expressed B.r. Cry tF delta endotoxin, and pollen from maize expressing B.r. Cry tF delta endotoxin	45 <mark>020108</mark>	68467	PER	
885 4340	Cry IF Bacillus thuringiensis Var. aizawai delta endotoxin: A dietary study with green lacewing larvae	45020109	68467	PER	
885.4340	Cry IF Bacillus thuringiensis var, aizawai delta endotoxin: A dietary study with the ladybird beetle	45020110	68467	PER	
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Mana	Date October 27, 2011	980000

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	D;	ATA MATRIX			
Date: October 27, 2011				EPA Reg. No./Fite Symbol: 68467-2	Page 23 of 66
Applicant's/Registrant's Name & Monsanto Company, 800	Address: N. Lindbergh Blvd., St. Louis, MO 63167			Product: Herculex® I Insect Prof	ection
Ingredient B.t. CrytF prote	ein and the genetic material necessary for production (plas	mid insert PI-IP8999	9) in maize (OECD Identi	ficr: DAS-Øt5Ø7-1)	
Guideline Reference Number	Guideline Study Namc	MRID Number	Submitter	Status	Note
885.4340	CrytF Bacillus thuringiensis var. aizawai delta endotoxin: A dietary toxicity study with parasitic hymenoptera	45020111	68467	PER	
71-2	Transgenic corn expressing Bactllus thuringtensis var. aizawai (B.r.) Cryl F delta endotoxin: A dietary toxicity study with Northern bobwhite	45020112	68467	PER	
	Field survey of beneficial arthropods associated with Bacillus thuringiensis Cry1F maize	45020113	68467	PER	
	Efficacy of Cry1F events TC1360 and TC1507	45020114	68467	PER	
	Cry1F binding studies	45020115	68467	PER	
	Resistance management plan for transgenic maize expressing the Cry1F insecticidal protein from Bacillus thuringiensis var. aizawai	45020116	68467	PER	
Signature See Page 1 for Signature		Name and Title J. Austin Bums, Plt.D Regulatory Affairs Ma			

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		ATA MATRIX			
Date: October 27, 2011			E	PA Reg. No./File Symbol: 68467-2	Page 24 of 66
Applicant's/Registrant's Name & Monsanto Company, 800 i	Address: N. Lindbergh Blvd., St. Louis, MO 63167		Į,	Vroduct: Herculex® I Insect Protection	
Ingredient B.t. Cry1F prote	ein and the genetic material necessary for production (plass	mid insert PHP8999	9) in maize (OECD Identitie	r: DAS-Ø15Ø7-1)	
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Supplement to MRID 44714801: Supplemental data - Product characterization data for <i>Bacillus thuringiensis</i> var. aizawai: Cry1F control protein as expressed in maize	45020117	68467	Irer	
	Supplement to MRID 4469 101: Supplemental data - Acute oral toxicity in mice: Bacillus thriringiensis var. aizawai Cryl F delta endotoxin	45020118	68467	PER	
	Phosphinothricin acetyltransferase (PAT) protein: In vitro digestibility study	45041501	68467	PER	
	Non-target exposure and risk assessment for environmental dispersal of Cry1F maize pollen	45041502	68467	PER	
	Evaluation of the dietary effect(s) on honeybee development using bacterially expressed B.t. Cry1F delta endotoxin and pollen from maize expressing B.r. Cry1F delta endotoxin	45041503	68467	PER	
	Waiver request: Fish toxicity test with transgertic maize (corn) containing Bacillus rluntingiensis var. aiaqoi (B.r.) Cry IF delta endotoxin	45044201	68467	PER	
Signature  See Page 1 for Signature  PA Form 8570-35 (9-97) Electronic and Pager versions available. Submit only Pager version			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Mana	Date October 27, 2011	

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Date: October 27, 2011				EPA Reg. No /File Symbol: 68467-2	Page 25 of 66
	N. Lindbergh Blvd., St. Louis, MO 63167	······	······	Product: Herculex® I Insect Pro	tection
	ein and the genetic material necessary for production (plas	mid insert PhrP8999	9) in maize (OECD Identif	ier: DAS-Ø[5Ø7-1)	
Guidetine Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
. San page many	High dose demonstration of Cry1F events fC1360 and TC1507: European corn borer	45131101	68467	PER	
	Toxicity of the Cryff protein to neonate larvae of the monarch buttefly (Danans plexippus (Linneaus))	45131102	68467	PER	
	Public interest document for Cryff-protected com	45[3]103	68467	PER	
	Thermotability of Cry1F (truncated) delta endotoxin	4527480t	68467	PER	
	Compositional analysis of maize MPS hybrid line 1507	45274802	68467	PER	
	Cry1F lateral flow test kit procedure for analyzing Cry1F corn grain	45279301	68467	PER	
	Method validation report for the determination of Cry1F delta endotoxin protein in grain by Enzyme-Linked Immunosorbent Assay	45279302	68467	PER	
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Man	Date October 27, 2011	

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Date: October 27, 2011	78444	N-What	I	EPA Reg. No./File Symbol: 68467-2	Page 26 of 66
	N. Lindbergh Blvd., St. Louis, MO 63167	······		Product: Herculex® I Insect Pro	otection
ngredient B.t. CrytF prote	ein and the genetic material necessary for production (plas	smid insert PHP8999	) in maize (OECD Identific	er: DAS-Øt5Ø7-1)	
Guideline Reference Number	Guideline Study Name	MRtD Number	Submitter	Status	Note
CL07 35074-551	Supplement to MRID 45131102: Supplemental data - High dose demonstration of Cry1F events TC1360 and TC1507: European eorn borer	4 <i>5</i> 30770 l	68467	PER	
	Waiver request: Fish toxicity test to assess the potential effects of maize containing Bacitlus thuringiensis var. aizawai (Bt) CrytF insecticidal protein (tCP) in native fish	4 <u>5</u> 307702	68467	PER	
	Supplement to MRID 45020109: Cry1F Bocillus thuringiensis var. aizawai delta endotoxin: A dietary toxicity study with green lacewing larvae	45307801	68467	PER	
	Supplement to MRtD 45020110: Cry1F Bocillus thuringtensis var, arzawai delta endotoxin: A dictary toxicity study with green ladybird beetle	45307802	68467	PER	
	Supplement to MRID 45020111: Cry VF Bacillus thuringiensis var. aizawai delta endotoxin: A dietary toxicity study with parasitic hymenoptera	45307803	68467	PER	
20 May 20	Supplement to MRID 45020 to6: Cryff Bacillus thuringtensis var, aizawai delta endotoxin; An acute toxicity study with the earthworm in an artificial soil substrate	45307804	68467	₽ER	
Signature See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Man.	Date October 27, 2011		

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Date: October 27, 2011 Applicant's/Registrant's Name &				EPA Reg. No /File Symbol: 68467-2	Page 27 of 66
	N. Lindbergh Blvd., St. Louis, MO 63167 ein and the genetic material necessary for production (plass	nid insert PHP8990		Product: Herculex® I Insect Pro	otection
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Supplement to MRID 45041503: Evaluation of the dictary effect(s) on honeybee development using bacterially expressed B.r. Cry1F delta endotoxin and pollen from maize expressing B.t. Cry1F delta endotoxin	45307805	68467	PER	
and the special section of the secti	Exposure and risk assessment of Herculex I Bt field compollen to Karner blue butterfly	45512901	68467	PER	
	Nutritional equivalency of B.r. Cry1F maize - poultry feeding study	45622001	68467	PER	
	Field survey of beneficial arthropods associated with Bacillus thuringiensis Cry1F maize	45648001	68467	PER	
	Field surveys of non-target invertebrate populations in B.r. com	45652001	80778	PER	
	Development and characterization of Enzyme-Linked Immunosorbent Assay (ELISA) for detection of Cry1F protein	45685601	68467	PER	
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Man	Date October 27, 2011	

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		ATA MATRIX	***************************************		
Date: October 27, 2011				EPA Reg. No/File Symbol: 68467-2	Page 28 of 66
Applicant's/Registrant's Name & Monsanto Company, 800	Address: N. Lindbergh Blvd., St. Louis, MO 63167			Product: Herctilex® 1 Insect Prot	eclion
	ein and the genetic material necessary for production (plass	mid insert PHP8999			
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Independent laboratory validation of method GRM 02.13, determination of Cry1F delta endotoxin protein in corn grain by an of Enzyme-Linked Immunosorbent Assay	45685602	68467	PER	
THE CONTRACT	Supplement to MRID 45131102: Toxicity of the Cry1F protein to neonale larvae of the monarch butterfly (Danaus plexippus (Luneaus))	45759701	68467	PER	
	Stewardship of Herculex I Insect Protection with respect to the secondary lepidopteran pest, western bean cutworn (Richia albicosta Smith)	45896501	68467	PER	
- 800 a	Lack of cross reactivity between Cry1F protein in Herculex I maize and the dust mite Der p7 protein with human sera positive for Der p7-IgE	46444001	68467	PER	
	Monitoring the susceptibility of European corn borer to CrylAb and CrylF Bt proteins: Results from the 2004 collections and diapausing larvae collected in 2003	46583101	80778	PER	
	Stewardship of event TC1507 maize with respect to the secondary lepidopteran pests lesser corn stalk borer (Elasmopalpus lignosellus Zeller), southern corn stalk borer (Diatraea crambidiodes Grote), and sugarcane borer (Biatraea saccharalis Fabricius)	46600201	68467	PER	
Signature	See Page 1 for Signature		Name and Title J. Auslin Burns, Ph.D. Regulatory Affairs Mar	Date October 27, 2011	

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	D/	ATA MATRIX			
Date: Oclober 27, 2011				EPA Rcg. No./File Symbol: 68467-2	Page 29 of 66
Applicant's/Registrant's Name & Monsanto Company, 800 l	Address: N. Lindbergh Blvd., St. Louis, MO 63167			Product: Herculex® I Insect Prote	ection
Ingredient B.t. Cry1F prote	ein and Ilic genetic material necessary for production (plass	mid insert PHP8999	9) in maize (OECD Identi	fier: DAS-Ø15Ø7-1)	
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Slide presentation summarizing European corn borer and Cry IF resistance monitoring update	46695801	68467	PER	
a specific and spe	Insect resistance management compliance assurance program report for corn borer-protected Bt corn	46747801	80778	PER	
	Field surveys of non-target invertebrate populations in Bt corn: Supplement to MRID No. 45652001	467 <b>8</b> 4601	80778	PER	
	Monitoring the susceptibility of corn lepidopteran pests to Cry1Ab and Cry1F proteins: 2005 monitoring results	46874901	80778	PER	
	Research results on 2004 European corn borer collections from Hamilton County, Iowa: Cry1F	47011201	68467	PER	
	Insect resistance management compliance assurance program report for corn borer-protected Bt corn, corn rootworm-protected Bt corn, and corn borer/corn rootworm protected stacked Bt corn	47044401	80778	PER	
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	Nashington, DC 20460. Do not send the form to this addres:  DA	TA MATRIX			
Date: October 27, 2011				EPA Reg. No./File Symbol: 68467-2	Page 30 of 66
	N. Lindbergh Blvd., St. Louis, MO 63167			Product: Herculex® I Insect P	rotection
Ingredient B.t. Cry1F prote	ein and the genetic material necessary for production (plass	mid insert PHP8999	9) in maize (OECD Identi	ifier: DAS-01507-t)	
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note_
	Monitoring the susceptibility of corn lepidopteran pests to Cry1Ab and Cry1F proteins: 2006 monitoring results	47118401	80778	PER	
	Soil accumulation of Cry1F after three years of cropping with Herculex 1 corn	47120701	68467	PER	
- Annie Company	TC1507 maize and fall armyworm in Pucno Rico	47176001	68467	PER	
	Proposed revisions to tRM-related registration requirements for Cry1 plant-incorporated protectants in field corn	47407001	80778	PER	
	Monitoring the susceptibility of corn lepidopteran pests to Cryl Ab and Cryl F proteins: 2007 monitoring results	47413901	80778	PER	
******	Proposed revisions to tRM-related registration requirements for Cry1 plant-inenrporated protectants in field corn	47543901	80778	PER	When the second
Signature	See Page 1 for Signature tronic and Paper versions available. Submit only Paper vers		Name and Title J. Austin Burns, Ph.D Regulatory Affairs M		

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	DA	TA MATRIX			
Date: October 27, 2011			E	PA Reg. No./File Symbol: 68467-2	Page 31 of 66
	N. Lindbergh Blvd., St. Louis, MO 63167			roduct: Herculex® 1 Insect Pro	otection
Ingredient B.t. Cry tF prot	ein and the genetic material necessary for production (plass	nid insert PHP8999	) in maize (OECD Identifier	: DAS-Ø15Ø7-1)	
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Monitoring the susceptibility of com lepidopteran pests to Cry (Ab and Cry (F proteins: 2008 monitoring results	47841801	80778	PER	
	Monitoring the susceptibility of corn lepidopteran pests to Cryl Ab and Cryl P proteins: 2009 monitoring results	47971001	80778	PER	
	Production Report and Certificate of Analysis of Truncated Cry1F (TSN104550)	48193001	68467	PER	,
	2010 Insect Resistance Management Compliance Assurance Program for Corn Borer Protected Bt Corn, Corn Rootworm Protected Bt Corn, and Corn Borer/Corn Rootworm-Protected Stacked Bt Corn	48375001	80778	PER	
	Enhanced Insect Resistance Management Compliance Assurance Program for Corn Borer Protected Bt Corn, Corn Rootworm Protected Bt Corn, and Corn Borer/Corn Rootworm-Protected Stacked Bt Corn	48375101	80778	PER	· · · · · · · · · · · · · · · · · · ·
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D.	Date October 27, 2011	

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	N. Lindbergh Blvd., St. Louis, MO 63167		Product: M				
	tein and the genetic material (vector ZMIR39) necessary			(OECD Uniqu		7-3}	
Guideline Reference Number	Guideline Study Name	MRIO Number	Submitter		Status	Note	
	Conditions of Registration for MON 88017 (EPA Reg. Nn.524-551) and MON 89034 x MON 88017 (EPA Reg. No.524-5761, and Response to EPA's Request for Additional Information on Monsanto's Resistance Conf. Rootwarm (CRW) Monitoring Program.	484368-01	Monsanto Com	pany	own	Terms & Conditions	
	Conditions of Registration for MON 88017 (EPA Reg. No. 524-551) and Conditions of Registration for MON 89034 x MON 88017 (EPA Reg. No. 524-576).	484368-01	Monsanto Com	pany	OWN	Terms & Conditions	
	Enhanced Insect Resistance Management Compliance Assurance Program for Corn Borer Protected Bt Corn, Corn Rootworm-Protected Bt Corn, and Corn Borer / Corn Rootworm Protected Stacked Bt Corn.	483751-01	ABSTC		PER	Terms & Conditions	
	Annual Sales Repart for MON 810, MON 863, MON 863 × MON 810, MON 88017, MON 88017 × MON 810, MON 89034, MON 88017 × MON 89034, and MON 88017 × MON 89034 × TC1507 × DAS-59122-7 (EPA Reg. Nos. 524-489, 524-528, 524-545, 524-551, 524-552, 524-575, 524-576, and 524-581)	483678-01	Monsanto Com	рапу	own	Terms & Conditions	
	2009 Season Mointoring for the susceptibility of Neonate Western Corn Rootworm Larvae to the Bacillus thin inglerisis Cry3Bb1 Protein.	N/A	Monsanto Com	pany	OWN	Terms & Conditions	
	2009 Season Monitoring for the Susceptibility of Neonale Western Corn Rootworm Larvae to the Bacillus thuringlensis Cry3Bb1 Protein.	482080-01	Monsanto Com	pany	OWN	Terms & Conditions	
Signature	See Page 1 for Signature		Nanie and Title J. Auslin Burns, Ph.D Regulatory Affairs		Date October 27, 2011		

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Date: Oclober 27, 2011			E	PA Reg. No./File Symbol: 524-551	Page 33 of 66
	N. Lindbergh Blvd., St. Louis, MO 63167			oduet: MON 88017	
tngredient B.t. Cry3Bb1 pro	tein and the genetic material (vector ZMIR39) necessary f	or its production in	event MON 88017 com (OF	ECD Unique Identifier: MON-88ØI	7-3)
Guideline Reference Number	Guideline Study Name	MRID Number	Subminer	Status	Note
	2009 Inseet Resistance Management Compliance Assurance Program Report for Corn Borer-Protected Bt Corn (EPA Reg. Nos. 524-489, 68467-2, 67979-1, and 29964-3), Corn Rootworm-Protected Bt Corn (EPA Reg. Nos. 524-528, 524-551, 68467-5, 67979-5, and 29964-4), and Corn Borer/Corn Rootworm-Protected Stacked Bt Corn (EPA Reg. Nos. 524-545, 524-552, 524-576, 68467-6, 67979-8, and 29964-5).	479710-01	ABSTC	PER	Terms & Conditions
	Annual Sales report for MON 810 (EPA Reg. No. 524- 489), MON 863 (EPA Reg. No. 524-528), MON 863 x MON 810 (EPA Reg. No. 524-545), MON 88017 (EPA Reg. No. 524-551), MON 89034 (EPA Reg. No. 524-575) and MON 89034 x MON 88107 (EPA Reg. No. 524-576).	479614-01	Monsanto Compan	y OWN	Terms & Conditions
	2008 Season Monitoring for the Susceptibility of Neonate Western Corn Rootworm Larvae to the Bacillus thuring tensis Cry3Bb1 Protein.	478846-01	Monsanto Compan	y OWN	Terms & Canditions
	2008 Insect Resistance Management Compliance Assurance Program Report for Com Borer-Protected Bt Corn (EPA Reg. Nos. 524-489, 68467-2, 67979-1, and 29964-3), Corn Rootworm-Protected Bt Corn (EPA Reg. Nos. 524-528, 524-551, 68467-5, 67979-5, and 29964-4), and Corn Borer/Corn rootworm-Protected Stacked Bt Corn (EPA Reg. Nos. 524-545, 524-552, 68467-6, 67979-8, and 29964-5).	476633-01	ABSTC	PER	Terms & Conditions
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Ma	Date October 27, 2011	; Commons

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	D/	ATA MATRIX			
Date: October 27, 2011		EPA Reg.	No. IFite Symbol: 524-551	Page 34 of 66	
Applicant's Registrant's Name & Address:  Monsanto Company, 800 N. Lindbergh Blvd., St. Lonis, MO 63167			Product: MON 88017		
Ingredient B.t. Cry3Bb1 pro	tein and the genetic material (vector ZMIR39) necessary	for its production in	event MON 88017 com (OECD Ur	ique Identifier: MON-8801	7-3)
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Annual Sales Report for YieldGard Com Borer Com (EPA Reg. No. 524-489), YieldGard Rootworm Com (EPA Reg. No. 524-528), YieldGard Plus Corn (EPA Reg. No. 524-545), MON 88017 (EPA Reg. No. 524-551), and MON 88017 × MON 810 (EPA Reg. No. 524-552).	47663 t-0	Monsanto Company	OWN	Terms & Conditions
	2006 Insect Resistance Management Compliance Assurance Program for Corn Borer-Protected Bt Corn, Corn Rootworm-Protected Bt Corn and Corn Borer/Corn Rootworn-Protected Stacked Bt Corn. (ABSTC Report).	470444-01	ABSTC	PER	Terms & Conditions
	Submission of Annual Sales Report for YieldGard* Corn Borer corn (EPA Reg. No. 524-489), YieldGard* Rootworm corn (EPA Reg. No. 524-528), YieldGard* Plus corn (EPA Reg. No. 524-545), MON 88017 (EPA Reg. No. 524-551) and MON 88017 x MON 810 (EPA Reg. No. 524-552), (2007).	470431-01	Monsanto Company	OWN	Terms & Conditions
	Susceptibility of Neonate Rootworm Larvae to the Cry3Bb1 toxin from Bacillus thuringiensis: 2005 Data Summary.	469491-01	Monsanto Company	OWN	Terms & Conditions
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date October 27, 2011	

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Date: October 27, 2011		EI	PA Reg. No./File Symbol: 524-551	Page 35 of 66	
Applicant's/Registrant's Name &			Pr	oduct: MON 88017	
	N. Lindbergh Blvd., St. Louis, MO 63167 tein and the genetic material (vector ZMIR39) necessary	For the weather in	- 2- 2- 2- 2- 2- 2- 2- 2- 2- 2- 2- 2- 2-	CD Uniona Linetifon MON 99(X)	17.2)
Guideline Reference Number		MRID Number	Submitter	Slatus	Note
Obligating Reference Number	Guideline Study Name	MIKID Mainder	Subinities	Status	Noie
885.1100	Sidhu, R. S. (2004). Human Health and Environmental Assessment of the Plant-Incorporated Protectant Bacillus thuringiensis Cry3Bb1 Protein Produced in MON 88017. MSL-18835	461817-01	Monsanto Company	own	Product Characterization
885.1100	Beasley, K. A., H.M. Anderson., P.B. Wimberley, D.W. Mittank., and R.P. Lirette (2002). Molecular analysis of YieldGard®Rootworm/Roundup Ready®Corn Event MON 88017. MSL-17609	461817-02	Monsanto Company	y OWN	Product Charactetization
885.1100	Bhakta, N. S., A. J. Hartmann, and J. C. Jennings (2003). Cry3Bb1 and CP4 EPSPS Protein Levels in Corn Tissues Collected from MON 88017 Corn Produced in U.S. Field Trials Conducted in 2002. MSL-18823	461817-03	Monsanto Company	own	Product Characterization
885.1100	Duan, J. J., M. S. Paradise and C. Jiang (2003).  Evaluation of Functional Equivalence of Two Cry3Bb1  Protein Variants Against Susceptible Colcopteran species.  MSL-18799	461817-04	Monsanto Compan	y OWN	Product Characterization
885.1100	Hileman, R. E. and I. D. Astwood (2001). Additional Characterization of the Cry3Bb1 Protein Produced in MON 863. MSL-17137	454240-10	Monsanto Compan	<del></del>	Product Characterization
Signature	See Page 1 for Signature		Name and Title J. Austin Bums, Ph.D. Regulatory Affairs Ma	Date October 27, 2011	

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Date: October 27, 2011		WA HEATTAIN		EPA Reg. No	/File Symbol: 524-551	Page 36 of 66
	N. Lindbergh Blvd., St. Louis, MO 63167			Product: M	ION 88017	
Ingredient B.t. Cry3Bb1 pro	stein and the genetic material (vector ZMIR39) necessary		event MON 88017 com	(OECD Uniq	ue Identifier: MON-8801	
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter		- Status	Note
885.1100	Hileman, R. E., G. Holleschak, L. A. Turner, R. S. Thoma, C. R. Brown and J. D. Astwood (2001). Characterization and Equivalence of the Cry3Bb1 Protein Produced by E. coli Fermentation and MON 863. MSL-17274	455382-01	Monsanto Com	pany	OWN	Product Characterization
860.1340	Brown, M. (2003). TrailChek <sup>TM</sup> Cry3Bb Lateral Flow Test Strip and SeedChek <sup>TM</sup> Cry3Bb ELISA Performance Verification for Corn Seed, Leaf, and Composite Testing. MSL-19581, in unpublished study conducted by Strategies Diagnostics, Inc.	463942-01	Monsanto Cnm	pany	OWN	Product Characterization
885.1100	Dudin, Y. A., B-P. Tonnu, L. D. Albec and R. P. Lirette (2001). Amended Report for MSL-16559: B.r. Cry3Bbt.11098 and NPTII Protein Levels in Sample Tissue Collected from MON 863 Grown in 1999 Field Trials. MSL-17181	454240-01	Monsanto Con	pany	OWN	Product Characterization
885.1100	Supplemental Information for "Evaluation of Functional Equivalence of Two Cry3Bb1 Protein Variants Against Susceptible Coleopteran Species" (MRID No. 461817-04)	465783-03	Mnasanio Com	pany	OWN	Product Characterization
885.1100	Thoma, R. S., G. Holleschak, R. E. Hileman and J. D. Astwnod (2001). Primary Structural Protein Characterization of MON 863 Cry3Bb1.11098 Protein Using N-terminal Sequencing and MALDI Time of Flight Mass Spectrometric Techniques. MSL-17154	454240~11	Monsanto Com	pany	OWN	Product Characterization
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D Regulatory Affairs		Date October 27, 2011	

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Date: October 27, 2011			EPA	A Reg. No./File Symbol: 524-55	Page 37 of 66
Applicant's/Registrant's Name & Monsanto Company, 800 I	Address: N. Lindbergh Blyd., St. Louis, MO 63167		Pro	duct: MON 88017	
Ingredient B.t. Cry3Bb1 pro	tein and the genetic material (vector ZMIR39) necessary t	for its production in	event MON 88017 com (OE)	CD Unique Identifier: MON-88Ø	7-3)
Guideline Reference Number	Guideline Study Name	MRID Number	Subminer	Status	Note
885.1100	Submission of Supplemental Data (May 21, 2001) in Support of the Application for Registration of MON 863: Corn Rootworm Protected Corn (Vector ZM(R13L); EPA File Symbol 524-LEI.	N/A	Monsanto Corupany	OWN	Product Characterization
885.1100	Dudin, Y., B-P. Tonnu and R. P. Lirette (2001). Cry3Bb1, Cry1Ab and NPTtt Protein Levels in the Dual- trait Maize Hybrid MDN 863 x MON 810 Produced in Argentinian Field Trials Conducted During the 1999-2000 Growing Season. MSL-17266	45 <u>7917-02</u>	Monsanto Company	OWN	Product Characterization
885.1100	Holleschak, G., T. C. Lee, R. E. Hileman, P. D. Pyla, and J. D. Astwood (2001). Amended Report for MSL-15835: Assessment of the Equivalence of B.r. Protein 11098, B.r. Protein 11231 and NPTII Protein Expressed in Corn Events MON 853 and MON 860 to Microbial Sources. MSL-17222	454240-04	Monsanto Company	OWN	Product Characterizatinn
885.1100	Supplemental Information for "Cry3Bb1 and CP4 EPSP8 Protein Levels in Corn Tissues Collected from MON 88017 Corn Produced in U.S. Field Trials Conducted in 2002" (MRID No. 461817-03)	465783-02	Monsanto Company	OWN	Product Characterization
885.1100	Holleschak, G., R. E. Hileman, and J. D. Astwood (2001). Amended Report for MSL-16596: Assessment of the Physicochemical Equivalence of Cry3Bb1.11098 and NPTII Proteins in Corn Event MON 863 to Microbial Sources. MSL-17220	454240-05	Monsanto Company	OWN	Product Characterization
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Man	Date October 27, 2011 ager	

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Applicant's/Registrant's Name &	Address: N. Lindbergh Blvd., St. Louis, MO 63167			Product: M		
	tein and the genetic material (vector ZMIR39) necessary	for its production is	event MON 88017 com			7-3)
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter		Status	Note
885.1100	Supplemental Information for "Molecular Analysis of YieldGard Rootworm/Roundup Ready" Corn Event MON 88017" (MRID No. 461817-02)	465783-01	Monsanio Com	pany	OWN	Product Characterization
860.1340	D. Kolwyck, B-P. Tonnu, Y. A. Dudin, T. Ploesser and K. Gustafson (2001). Validated Method for Extraction and Direct ELISA Analysis of Cry3Bb1 in Corn Grain. Monsanto Ref. No. 99-640E-1.	453731-01	Monsanto Com	pany	own	Product Characterization
N/A	Astwood, J. D., R. E. Hileman, M. J. McKee, T. J. Rydel, J. W. Seale and L. English (2001). Safety Assessment of Cry3Bbt Variants in Com Rootworm Protected Com. MSL-17225	454240-09	Monsanto Com	pany	OWN	Human Health Assessment
885.1100	Hileman, R. E., J. N. Leach and J. D. Astwood (2001). Assessment of the <i>in vitro</i> Digestibility of Cry3Bb1.11098(Q349R) Protein in Simulated Intestinal Fluid. MSL-17530	455770-02	Monsanto Com	pany	OWN	Human Health Assessment
885.1100	Holleshak, G., R. E. Hileman and J. D. Astwood (2001). Amended Report for MSL-16597: Immunodetectability of Cry3Bbt.11098 and Cry3Bbl.11231 Proteins in the Grain of Insect Protected Com Events MON 863 and MON 853 After Heat Treatment. MSL-17223	454240-07	Monsanto Com	pany	OWN	Human Health Assessment
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D Regulatory Affairs		Date October 27, 2011	***************************************

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Date: October 27, 2011			EPA R	eg. No./File Symbol: 524-551	Page 39 of 66
	N. Lindbergh Blvd., St. Louis, MO 63167			t: MON 88017	
	tein and the genetic material (vector ZMIR39) necessary		T		
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.3050	Bechtel, C. L. (1999). Acute Oral Toxicity of B.r. Protein 11231 in Mice. MSL-16216.	449043-05	Monsanto Company	OWN	Human Health Assessment
885.1100	Hileman, R. E., E. A. Rice, R. E. Goodman and J. D. Astwood (2001). Bioinformatics Evaluation of the Cry3Bbl Protein Produced in MON 863 Utilizing Allergen, Toxin and Public Domain Protein Databases. MSL-17140	454240-08	Monsanto Company	OWN	Human Health Assessment
885.3050	Bonnette, K. L. and P. D. Pyla (2001). An Acute Oral Toxicity Study in Micc with E. coli Produced Cry3Bb1.11098(Q349R) Protein, Amended Final Report. MSL-17382	455382-02	Monsanto Company	OWN	Human Health Assessment
885,t100	Leach, J. N., R. E. Hileman and J. D. Astwood (2001) Assessment of the in vitro Digestibility of Cry3Bb1 Protein Purified from MON 863 and Cry3Bh1 Protein Purified from E. coli. MSL-17292	455382-03	Monsanto Company	OWN	Huntan Health Assessment
885.3050	Bechtel, C. L. (1999). Acute Oral toxicity of B.r. Protein 11098 in Micc. MSL-16215	449043-06	Monsanto Company	DWN	Human Health Assessment
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manag	Date October 27, 2011	

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Date: October 27, 2011			\ E	PA Reg. No./File Symbol: 524-551	Page 40 of 66
	N. Lindbergh Blvd., St. Louis, MO 63167			roduct: MON 88017	
Ingrediem B.t. Cry3Bb1 prof	tein and the genetic material (vector ZMIR39) necessary I	or its production in	event MON 88017 com (O	ECD Unique Identifier: MON-8801	7-3)
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Hileman, R. E. and J. D. Astwood (1999). Bioinformatics Analysis of B.t. Protein 11098 and B.r. Protein 11231 Sequences Utilizing Toxin and Public Domain Genetic Databases. MSL-15870	449043-08	Monsamo Compar	y OWN	Human Health Assessment
885.1100	Hileman, R. E. and J. D. Astwood (1999). Bioinformatics Analysis of B., Protein 11098 and B., Protein 11231 Sequences Utilizing an Allergen Database. MSL-15873	449043-09	Monsamo Compar	ıy OWN	Human Health Assessment
885.1100	Leach, J. N., R. E. Hileman, J. W. Martin, R. S. Thoma, and J. D. Astwood (2001). Amended Report for MSL-15704: Assessment of the <i>In Vitra</i> Digestibility of <i>B.</i> 1. protein 11098 and <i>B.</i> 1. 11231 Utilizing Mammalian Digestive Fate Models. MSL-17166	454240-06	Monsanto Compar	ıy OWN	Human Health Assessmem
885.4200	McKee, M. J. (2001). Bluegill Dietary Toxicity Study for the Bacillus thuringiensis Cry3Bb1 Protein Variant: A Waiver Request. MSL-17383	455382-00	Monsanto Compar	iy OWN	Environmental Assessment
885.4240 Series 72, Subdivision E	Drottar, K. R. and H. O. Krueger (1999). Boculus thuringiensis Protein 11098 in Com Pollen: 48-Hour Static Renewal Acute Toxicity Test with the Cladoceran (Daphnia tragna). MSL-16163	449043-18	Monsamo Compar	oyOWN	Environmemal Assessmem
Signature	See Page 1 for Signature	2000	Name and Title J. Aussin Burns, Ph.D. Regulatory Affairs Ma	Date October 27, 2011	

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Date: October 27, 2011			EľA	Reg. No./File Symbol: 524-551	Page 41 оГ 66
	N. Lindbergh Blvd., St. Louis, MO 63167		Produ	uet: MON 88017	
Ingredient B.t. Cry3Bb1 prot	tein and the genetic material (vector ZMIR39) necessary	for its production in	event MON 88017 com (OEC)	D Unique Identifier: MON-88Ø	17-3)
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4280	Results of acute toxicity tests with Daphnia and catfish did not produce any evidence of adverse effects.  Estuarine and Marine animal studies are waived for this product because of the very low to no potential for exposure to Cry3Bb1 protein from field corn.	N/A	Monsanto Company	OWN	Environmental Assessment Waived in BRAD
885.4340	Texiera, D. (2005), Evaluation of Dictary Effects of a Cry3Bb1 Protein Variant on Minute Pirate Bugs (Orius institiosus), MSL-19697	464799-05	Monsanto Company	OWN	Environmental Assessment
885.4300	Since the active ingredient in this product is an insect toxin (Bt endotoxin) that has never shown any toxicity to aquatic or terrestrial plants, these studies have been waived for this product. The Agency has determined there is no significant risk of gene capture and expression of Cry3Bb1 protein by wild or weedy relatives of corn.	N/A	Monsanto Company	OWN	Environmental Assessment Waived in BRAD
885.4340	Palmer, S. J. and H. O. Krueger (1999). Bacillus thuring lensis Protein 11231: Dietary Toxicity Study with the Ladybird Beetle (Hippodannia convergens). MSL-16166	449043-14	Monsanto Company	OWN	Environmental Assessment
850.6200	Hoxler, K. A., S. J. Palmer and H. O. Krueger (1999).  Bacillus rhuringiensis Protein 11231: An Acute Toxicity Study with Earthworm in an Artificial Soil Substrate, MSL-16162	449043-16	Monsanto Company	OWN	Environmental Assessment
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Mana	Date October 27, 2011 ger	

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tngredient B.t. Cry3Bb1 pro	tein and the genetic material (vector ZM1R39) necessary I	or its production in	event MON 88017 corn (O	ECD Unique Identifier: MON-886	17-3)
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Teixeira, D. (1999). Assessment of Chronic Toxicity of Corn Tissue Containing the Bacithis thirringiensis Protein 11098 to Collembola (Falsonio candida). MSL-15988	449043-17	Mansanto Compa	ny OWN	Environmental Assessment
885.4340	Palmer, S. J. and H. O. Krueger (1999). Bacillus thuringiensis Protein 11231: A Dietary Study with Green Lacewing Larvae (Chrysoperla carnea). MSL-16165	449043-12	Monsanlo Compa	ny OWN	Environmental Assessment
885,4340	Palmer, S. J. and H. O. Krueger (1999). Bacillus thuringiensis Protein 11231: A Dietary Study with the Parasitic Hymenoptera (Nasonia vitripennis). MSL-16167	449043-13	Monsanto Compa	ny OWN	Environmental Assessment
885.5200	Dubelman, S., M. Bhatti, B. Ayden, J. Murphy, S. Levine and C. Jiang (2005). Environmental Fate of Cry3Bb1 Protein in Corn Fields Planted with MON 863. MSL-19285	465103-01	Monsanto Compa	ny OWN	Environmental Assessment
<b>88</b> 5.4340	Duan, J. J., G. Head, M. McKee and T. E. Nickson (2001). Dietary Effects of Transgenic Bacitlus thuringiensis (Bt) Corn Pollen Expressing a Variant of Cry3Bbt Protein on Adults of the Ladybird Beetle, Coleomegilla maculata. MSL-16936	453613-01	Monsanio Compa	ny OWN	Environmental Aysessment
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs M	Date October 27, 2011	

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·······	tein and the genetic material (vector ZMIR39) necessary f				
Suideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Bryan, R. L., J. R. Porch and H. O. Krueger (2001). Dietary Effects of Transgenic BT Corn Pollen Expressing a Variant of Cry3Bb1 Protein on the Ladybird Beetle,  Hippodamio convergens. MSL-17171	453613-02	Monsanto Company	own	Environmental Assessment
t54-3500	Bhatti, M. A., C. L. Pilcher, M. J. McKee, T. E. Nickson, G. P. Head and C. D. Pilcher (2001). Field Evaluation for the Ecological Impact of Corn Rootworm Insect-Protected Corn on Non-Target Organisms. MSL-17179	455382-06	Monsanto Company	OWN	Environntental Assessment
885.4340	Duan, J. J., M. J. McKee and T. E. Nickson (2001). Dictary Effects of Transgenic Bacillus thuringlensis (Bt) Corn Pollen Expressing a Variant of Cry3Bb1 Protein on Larvae of the Ladybird Beetle, Coleomegilla macullata. MSL-16907	455382-04	Monsanto Company	OMN	Environmental Assessment
885.4340	Scars, M. and M. Mattila (2002). Determination of the Toxicity of Corn l'ollen Expressing a Cry3Bbt Variant Protein to First Instar Monarch Butterfly Larvae (Donus plexippus) via Laboratory Bioassay. MSL-17235	455382-05	Monsanto Company	DWN	Environniental Assessment
N/A	Head, G., M. Pleau, S. Sivausupramanian and T. Vaughn (2001). Insecticidal Spectrum of Activity for Cry3Bb Protein in vitro. C3NTO	455382-07	Monsanto Company	OWN	Environmental Assessment
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date October 27, 2011	

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	N. Lindbergh Blvd., St. Louis, MO 63167	······		MON 88017	
Ingredient B.t. Cry3Bb1 prot	tein and the genetic material (vector ZMIR39) necessary	for its production in	event MON 88017 corn (OECD U	nique Identifier: MON-88Ø1	7-3)
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
n/a	Duan, J. J., M. J. McKee, G. Head and C. R. Brown (2002). Endangered Species Impact Assessment for Cry3Bb1 Protein in Transgenic MDN 863. MSL-17614	455770-03	Monsanto Company	OWN	Environmental Assessment
154-2300	Head, G. (2002). Research on the Effects of Corn Rootworm Protected Transgenic Corn Events on Nontarget Organisms: Preliminary Results. Monsanto Reference No. 00-CR-032E-7	456530-03	Monsanto Company	OWN	Environmental Assessment
154-3500	Bhatti, M. A., J. D. Duan, C. L. Pilcher, M. J. McKee, T. E. Nickson, G. P. Head and C. Jiang (2002). Ecological Assessment of Nontarget Organisms in the Plots of Corn Rootworm Insect Protected Com Hybrid Containing MDN 863 Event: 2000 - 2001 Field Trials. Report MSL-17531	457916-01	Monsanto Company	OWN	Environmental Assessment
850.6200	Sindermann, A. B., J. R. Porch and H. D. Krueger (2002). Evaluation of a Cry3Bb1 Protein Variant in an Acute Toxicity Study with the Earthworm in an Artificial Soil Substrate. MSL-18137	457571-01	Monsanto Company	OWN	Environmental Assessment
885.4050	Gallagher, S. P., J. Grimes and J. B. Beavers (1999).  Bacillus thuringiensis Protein 11231 in Corn Grain: A Dietary Toxicity Study with the Northern Bobwhite.  MSL-16161	449043-15	Monsanto Company	OWN	Environmental Assessment
Signature	See Page 1 for Signature		Name and Title J. Austin Bunts, Ph.D. Regulatory Affairs Manager	Date October 27, 2011	

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Applicant's/Registrant's Name & Monsanto Company, 800 1	Address: N. Lindbergh Blvd., St. Louis, MO 63167	200105	Produc	et: MON 88017	
Ingredient B.I. Cry3Bb1 pro	tein and the genetic material (vector ZMIR39) necessary t	for ils production in	event MON 88017 com (OECD	Unique Identifier: MON-88Ø1	7-3)
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885,4380	Maggi, V. L. (1999). Evaluation of the Dietary Effect(s) of Purified <i>Bacillus thuringlensis</i> Protein 11231 on Adult Honcy Bees ( <i>Apis utellifera</i> L.). MSL-16169	449043-11	Monsanto Ctimpany	OWN	Environmental Assessment
885.5200	Martin, J. W., M. J. McKee, S. Dubelman and Y. A. Dudin (2000). Acrobic Soil Degradation of the B.r. Protein 11098 as a Component of Insect Protected Chin. MSL-16440	451568-04	Monsanto Company	OWN	Environmental Assessment
885.5200	Dubelman, S., B. Ayden, M. Mueth, J. A. Warren, C. frang, J. Bookout and Y. Dudin (2002). Aerobic Soil Degradation of the <i>Bacillux thuringiensis</i> Cry3Bbl Variant Protein Produced in Corn Rootworm Protected MON 863. MSL-17102	457571-02	Monsanto Company	own	Environmental Assessment
885.4050	George, B. (2001). Comparison of Broiler Ferformance When Fed Diets Containing Events MON 863, Parental Line or Commercial Corn. MSL-17243	459415-01	Monsanto Company	OWN	Environmental Assessment
885.4380	Maggi, V.L. (1999). Evaluation of the Dietary Effects of Purified <i>Bacithus thuringiensis</i> Protein 11231 on Honey Bee Larvae. MSL-16168	449043-10	Mousanto Company	OWN	Environmental Assessment
885.5200	Dubelman, S., B. Ayden, J. Colyer, B. Ledesma, S. Levine, F. Lloyd, G. Mueller, J. Warren & C. Jiang (2007) Environmental Fate of the Cry3Bb1 and Cry1Ab Proteins in Com Fields Planted with MON 863 x MON 810 for Three Consecutive Years MSL-20589	472829-02	Monsanto Company	OWN	Environmental Assessment
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manag	Date October 27, 2011 er	

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Applicant's/Registrant's Name & Monsanto Company, 800 1	Address: N. Lindbergh Blyd., St. Louis, MO 63167		Prod	uet: MON 88017	
ngredient B.t. Cry3Bb1 pro	tein and the genetic material (vector ZMIR39) necessary f	or its production in	t event MON 88017 com (OEC	D Unique Identifier: MON-88Ø1	7-3)
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
154-3500	Duan, J., M. Bhatti, C. Brown, G. Head, C. Jiang, C. Pileher, C. Pileher, D. Carson & T. Niekson (2007) Two Year Field Assessment of the Effect of Combined Trail Bt Com Mon 863 x MON 810. MSL-19696	472829-01	Monsanto Company	OWN	Environmental Assessment
154-3500	Duan J. J., C. Jiang, M.J. McKee, M.A. Nemeth, D. Ward, G. Head, S. Levine, M. Bhatti and M. Paradise (2004). Statistical Power Analysis of a Two-Year Field Study Evaluating the Ecological Effect of Corn Event MON 863. MSL-19246	462627-03	Monsanto Company	OWN	Environmental Assessment
154-3500	Duan J. J., C. Jiang, C. Brown, M. Bhatti, M. Nemeth, T. Niekson and D. Ward (2004). Supplemental Statistical Analysis of Data from a Two-Year Field Census Study with Corn Event MON 863. MSL-19329	463942-02	Monsanto Company	OWN	Environmental Assessment
885.5200	Dubelman S., M. Bhatti and B. Ayden (2004). Interint Repon: Assessment of the Environmental Fate of the Cry3Bb1 Protein in Corn Fields Planted with MON 863. MSL-18931	462001-01	Monsanto Company	OWN	Environmental Assessment
885.4340	Duan J. and M. Paradise (2005). Evaluation of Dietary Effects of Cry3Bb1 Protein on the Ground Beetle Poecifus chalcies (Colecoptera Carabidae). MSL-19631	464799-04	Monsanto Company	OWN	Environmentat Assessment
154-3500	Head, G. (2004). Research on the Effects of Corn Rootworm Protected Transgenic Corn on Non-Target Organisms: Publications & Manuscripts.	462627-02	Monsanto Company	OWN	Environmental Assessment
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Mana	Date October 27, 2011	- 141

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Applicant's/Registrant's Name & Monsanto Company, 800 I	Address: V. Lindbergh Blvd., St. Louis, MO 63167		Product:	MON 88017	
Ingredient B.t. Cry3Bb1 pro	tein and the genetic material (vector ZMIR39) necessary t	or its production in	event MON 88017 corn (OECD U	nique Identifier: MON-880	7-3)
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4150	Manmalian wildlife exposure to Cry3Bb1 protein is considered likely; however, the Cry3Bb1 taxicity data for Human Health Assessment indicate that there is no significant toxicity to redents form testing at the maximum hazard dose. Therefore no hazard to mammalian wildlife is anticipated.	N/A	Monsanto Company	OWN	Environmental Assessment Waived in BRAD
885.4200	Li, M. H. and E. H. Robinson (1999). Evaluation of Insect Protected Corn Lines MON 853 and MON 859 as a Feed Ingredient for Catfish. MSL-16164	449043-19	Monsante Company	OWN	Environmental Assessment
885.4340	Duan, J. J., G. Head, M. J. McKee and D. P. Ward (2003).  Data Waiver Request: Toxicity of B.t. Cry3Bb1 Protein in the Red Milkweed Beetle (Terraapes sp.). MSI-18741	N/A	Monsanto Company	OWN	Environmental Assessment Granted in BRAD
N/A	Pilcher, C. D. (2001). Efficacy of MDN 863 Against Corn Rootworm and Comparison to Insecticide Treatments – Results of Year 2000 Field Trials. Monsanto Ref. No. 00-CR-032E-3	453613-03	Monsanto Company	OWN	Benefits
N/A	Mitchell, P. D. (2002). Yield Benefit of MON 863. MSL-17782	456530-02	Monsanto Company	OWN	Benefits
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date October 27, 2011	

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Guideline Reference Number	Guideline Study Name Ward, D. P. (2002). Public Interest Assessment	MRID Number	Submitter		Status	Note
N/A	Supporting Registration of Bacillus thuringiensis Cry3Bb1 Protein and the Genetic Material (Vector ZMIR13L) Necessary for its Production in MON 863. MSL-17766	456530-01	Monsanto Compa	ny	own	Benefits
N/A	Miller, D. (2000). Public Interest Document Supporting the Registration and Exemption from the Requirement of a Tolerance for the Plant-Incorporated Protectant, Bacillus fluringiensis Cry3Bb Protein, and the Genetic Material Necessary for its Production in Corn (Vectors ZMIR12L, ZMIR13L and ZMIR14L). Monsanto Ref. No. 99-781E	450297-01	Monsanto Compa	ny	OWN	Benefits
N/A	Alston, I. M., J. Hyde and M. C. Marra (2002). An Ex Ante Analysis of the Benefits from the Adoption of Monsanto's Corn Rootworm Resistant Varietal Technology - YieldGard® Rootworm. MSL-17993	456923-01	Monsanlo Compa	my	OWN	Benefits
N/A	Vaughn, T. T., M. Pleau, R. Knntson and T. Coombe (2001). Comparing the Efficacy of MON 853 and MON 863 to Three Corn Rootworm Species, Northern Corn Rootworm (Diabrotica barbert), Southern Corn Rootworm (D. undecimpunctara howardi), and Western Corn Rootworm (D. virgifera virgifera). MTC RPT4	455382-08	Monsanto Compa	iny	OWN	Benefins
N/A	Vaughn, T., D. Ward, J. Pershing, G. Head and J. McFerson (2001). An Interim Insect Resistance Management Plan for MON 863: A Transgenic Corn Rootworm Control Product. MSL-17556	455770-01	Monsanto Compa	uny	own	Benefus/IRM
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ngredient B.t. Cry3Bb1 pro	tein and the genetic material (vector ZMIR39) necessary f	or its production in	event MON 88017 com (OECI	Unique Identifier: MON-88ØI'	7-3)
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	Vaughn, T. (2004). Progress Repon on Insect Resistance Management for Com Event MON 863	461865-01	Monsanto Company	OWN	1RM
N/A	Vauglin, T. (2001). Preliminary Results of Research on Insect Resistance Management for a Transgenic Corn Rootworm Control Product.	453484-01	Monsanto Company	OWN	IRM
N/A	Head, G. and K. Reding. (2006). Corn rootworm Insect Resistance Management Research (fourteen journal publications)	467 <b>424</b> -01	Monsanto Company	OWN	IRM
N/A	Davis, P., G. Head, J. McFerson et. al. (2000). Insect Resistance Management for a Transgenic Com Rootworm Control Product.	451568-05	Monsanto Company	OWN	IRM
N/A	Vauglin, T. (2003). Estimating Cry3Bb1 Resistance Allele Frequencies in Corn Rootworm Larvae Feeding on MON 863. Monsanto Ref. No. 03-CR-097E-4	459438-01	Monsanto Company	own	IRM
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manag	Date October 27, 2011	14230

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**************************************	DA	TA MATRIX			
Date: October 27, 2011				EPA Reg. No./File Symbol: 524-551	Page 50 of 6
Applicant's/Registrant's Name & Monsanto Company, 800 ì	Address: N. Lindbergh Blvd., St. Louis, MO 63167		- 1100	Product: MON 88017	
Ingredient B.t. Cry3Bb1 pro	tein and the genetic material (vector ZMIR39) necessary f	or its production in	event MON 88017 corn (	OECD Unique Identifier: MON-88Ø1	7-3)
Guideline Reference Number	Guidefine Study Name	MRID Number	Submitter	Status	Note
N/A	T. Vaughn (2005). Second Progress Report on Insect Resistance Management for Corn Event MON 863. REVISED	N/A	Monsanto Comp	any OWN	İRM
N/A	Letter submitted May 23, 2003 to EPA with 12 research protocols on the biology and ecology of the corn rootworm pest complex.	N/A	Monsanto Comp	any OWN	<u>trm</u>
N/A	Vaughn, T. (2004). 2004 Progress Report for the Corn Event MON 863 Resistance Monitoring Program.	462627-01	Monsanto Comp	any OWN	1RM
N/A	Administrative Materials in Support of the Registration of Bacillus thuringiensis Cry3Bb Protein and the Genetic Material (Vector ZMtR13L) Necessary for its Production in Corn; and Amendment of the Previous Request for Exemption from the Requirement of a Tolerance, PP7F4888	451568-00	Monsanto Comp	any OWN	Tolerance Exemption
N/A	Pilacinski, W. P. and M. W. Taylor (1999).  Administrative Materials in Support of the Registration of the Plant-Expressed Protectant Bacillus thuringiensis. Corn Rootworm Control Protein, as Produced in the Corn (Zea mays, L.), and the Amendment to the Previous Request for Exemption from the Requirement of a Tolerance, PP7F4888	449043-00	Monsanto Comp	any OWN	Tolerance Excuption
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs M	Date October 27, 2011	

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1 102	DA	TA MATRIX				
Date: October 27, 2011				EPA Reg. No	/File Symbol: 524-551	Page 51 of 66
Applicant's/Registrant's Name & Monsanto Company, 800	Address: N. Lindbergh Blvd., St. Louis, MO 63167			Product: N	10N 88017	
Ingredient B.t. Cry3Bb1 pro	tein and the genetic material (vector ZMIR39) necessary f	or its production in	event MON 88017 com	(OECD Uniq	ue Identifier: MON-8801	7-3)
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter		Status	Note
N/A	Petition for Exemption from the Requirement of a Tolerance for Bacilfus tharingiensis Cry1, Cry2, and Cry3 Classes of Proteins and the Genetic Material Necessary for the Production of These Proteins In or Dn All Raw Agricultural Commodities When used as Plant-Pesticide Active Ingredients.	PP 7F4888	Monsanto Com	pany	own	Tolerance Exemption
885.1100	McCoy, R. L. and A. Sivanovich (2003). Bioinformatics Analysis of the CP4 EPSPS Protein Utilizing the AD4, TOXINS and ALLPEPTIDES Databases. MSL18752	466361-01	Monsanta Company		OWN	Inert Ingredient
885 1100	McCoy, R.L. and A. Sivanovich (2005). Updated Bioinformatics Evaluation of the CP4 EPSPS Protein Utilizing lhe AD5 Database. MSL19894	466361-02	Monsanto Com	pany	DWN	Inert Ingredient
885.3050	Monsanto Company (1995). Submission of Toxicology Data in Support of a Tolerance Petition for CP4 EPSPS as a Plant Pesticide Formulation Inert Ingredient. Transmittal of 1 Study.	436919-00	Monsanto Com	pany	OWN	tnert Ingredient
885.3050	Harrison, L., M. Bailey, D. Nida, M. Taylor, L. Holden and S. Padgette (1993). Preparation and Confirmation of Doses for an Acute Mouse Feeding Study With CP4 EPSPS. Lab Project Numbers: 92-01-30-12: 92-419-719	436919-01	Monsanto Com	рану	OWN	Inert Ingredient
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs 1		Date October 27, 2011	

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Date: October 27, 2011	9000000 90000000 900000 90000 9000000 9000000	- Chichell (1990) — Alt — Chichell (1990)		EPA Reg. No./File Symbol: 524-5	51 Page 52 of 66
Applicant's/Registrant's Name & Monsanto Company, 800 1	Address: N. Lindbergh Blvd., St. Louis, MO 63167			Product: MON 88017	~~~
ngredient B.t. Cry3Bb1 pro	tein and the genetic material (vector ZMtR39) necessary t	or its production in	event MON 88017 corn (	OECD Unique Identifier: MON-	88Ø17-3)
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Padgette, S., G. Barry, D. Re, D. Eichholtz, M. Weldon, K. Kolacz and G. Kishore (1993). Purification, Cloning, and Characterization of a Highly Glyphosate-Tolerant 5-enolpyruvylshikimate-3-phosphate Synthase from Agrobacterium sp. Strain CP4. MSL-12738	438076-01	Monsanto Comp	any OWN	Inert Ingredien
885.1100	Bishop, B. (1993). Production of CP4 EPSP in a 100 Liter Recombinant Escherichio coli Fermentation. MSL- 12389	438076-02	Monsanto Comp	any OWN	tnert Ingredien
885.1100	Heeren, R., S. Padgette and M. Gustafson (1993). The Purification of Recombinant Escherichia coti CP4 5-enolypyruvylshikimate-3-phosphate synthase for Equivalence Studies. MSL-12574	438076-03	Monsanto Comp	any OWN	Inert Ingredien
N/A	Monsanto Company (1995). Submission of Product Chemistry, Toxicology and Pesticide Fate in Animals Data in Support of the Exemption for the Requirement of a Petition for Tolerance for CP4 EPSPS. Transmittal of 4 studies.	436433-00	Monsanto Comp	nany OWN	Inert Ingredient
885.1100	Harrison, L., M. Bailey, R. Leimgruber, C. Smith, D. Nida, M. Taylor, M. Gustafson, B. Heeren and S. tradgette (1993). Characterization of Microbially-Expressed Protein: CP4 EPSPS. Lab Project Number: 92/01/30/14; 12901	436433-01	Monsanto Comp	any OWN	luert Ingredient
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs M	Date October 27, 201 Manager	1

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	DA	ATA MATRIX			
Date: October 27, 2011			EPA (Re	3 No./File Symbol: 524-551	Page 53 of 66
	N. Lindbergh Blvd., St. Louis, MO 63167			MON 88017	
	tein and the genetic material (vector ZMIR39) necessary				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Lee, T., M. Bailey, C. Smith, J. Zeng, E. Elswick and P. Sanders (1995). Assessment of the Equivalence of CP4 EPSPS Protein Produced in <i>Escherichia coti</i> and European Com Borer Resistant Corn. Lab Project Number: 94-01-39-10: MSL-13920	436433-02	Monsanto Company	OWN	Inert Ingredient
885.3050	Naylor, M. (1993). Acute Oral Toxicity Study of CP4 EPSPS in Albino Mice. Lab Project Number: 92223	436433-03	Monsanto Company	OWN	Inert Ingredient
885.1100	Ream, J., M. Bailey, J. Leach and S. Padgette (1993). Assessment of the in vitro Digestive Fate of CP4 EPSPS Synthase. Lab Project Number: 92-01-30-15: 12949	436433-04	Monsanto Company	OWN	friert Ingredient
N/A	Revisions and Clarification to the Terms & Conditions of Registration for Corn Event MON 863 and YieldGard* Plus Corn, Progress Report on Multiple IRM-Related Activities for MON 863, and Response to EPA Letter Dated August 13, 2004. Submitted 7/7/2005.	N/A	Monsanto Company	OWN	Terms & Conditions
N/A	Siegfried, B. and T. Speneer (2005). Susceptibility of Neonate Rootworm Larvae to the Cry3Bb1 Toxin from Bacillus rhuringinesis. This report satisfies the Insect Monitoring Terms & Conditions.	467259-01	Monsanto Company	OWN	Terms & Conditions
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Managet	Date October 27, 2011	

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Date: October 27, 2011				EPA Reg. No/File Symbol: 68467-5	Page 54 of 66
	N. Lindbergh Blvd., St. Louis, MO 63167		The second secon	Product: Herculex® RW Insect Pr	
Ingredient B.t. Cry34Ab1 a 59122-7)	and Cry35Ab1 Insecticidal Crystal protein and the genetic	material necessary i	for its production (plasmid	insert PHP17662) in com (OECD Idea	itifier: DAS-
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Nole
	Product characterization data for Bacillus thuringtensis PS149B1 13.6 kDa and 43.8 kDa insecticidal crystal proteins expressed in transgenic maize plants	45242201	68467	PER	
	Equivalency of microbial and maize-expressed PS149B1 proteins	45242203	68467	PER	
	Microbial PS (49B1 Binary Delta-Endotoxin: Maize- Insect-Post Susceptibility Study	45242204	68467	PER	
	Comparison of the Amino Acid Sequence of the Bacillus thuringiensis Strain PS149B1 13.6 kDa and 43.8 kDa Insecticidal Crystal Proteins to Known Protein Altergens	45242205	68467	yer	
	Characterization of Pseudomonas produced and transgenic maize expressed phosphinothricit acetyltransferase (PAT) protein	45242206	68467	PER	
	PS149B1-14 KDA Protein: Acute Oral Toxicity Study in CD-1 Mice	45242207	68467	PER	
Signature See Page 1 for Signature			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Mar	Date October 27, 2011	*300000*

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Date: October 27, 2011	1 1000000	20000000	E	PA Reg. No /File Symbol: 68467-5	Page 55 of 66
	N. Lindbergh Blvd., St. Louis, MO 63167			roduct: Herculex® RW Insect Pr	
Ingredient $B.t.$ Cry34Ab1 a 59122-7)	nd Cry35Ab1 Insecticidal Crystal protein and the genetic	material necessary t	for its production (plasmid in	sert PHP17662) in com (OECD Idea	ntifier: DAS-
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	PS149B1 44 KDA Protein: Acute Oral Toxicity Study in CD-1 Mice	45242208	68467	PER	
	PS149Bt 14 KDA and 44 KDA Proteins: Acute Oral Toxicity study in CD-I Mice	45242209	68467	PER	
	PS149B1 Binary Insecticidal Crystal Protein: A Dictary Toxicity Study with the Ladybird Beetle	45242210	68467	1 <sup>1</sup> ER	
	The Tri-Trophic Interaction Between PS149B1 Transformed Maize, Corn Leaf Aphid and Ladybird Beetle	45242211	68467	PER	
Web-	In Vitro Digestibility of PS149B1 Proteins	45242212	68467	PER	
	Quantitative ELtSA analysis of PS149B1 protein expression levels in hybrid and inbred lines of maize event TC5639 (interim report)	45242213	68467	PER	
Signature	See Page 1 for Signature		Name and Title J. Austin Bunis, Ph.D. Regulatory Affairs Mana	Date October 27, 2011	3 12 00000 3

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Date: Oetober 27, 2011		498	EPA Reg	No./File Symbol: 68467-5	Page 56 of 66
	N. Lindbergh Blvd., St. Louis, MO 63167			Herculex® RW Insect F	
ngredient B.t. Cry34Ab1 a 59122-7)	nd Cry35Ab1 Insecticidal Crystal protein and the genetic r	naterial necessary (	or its production (plasmid insert PI	IP17662) in com (OECD lde	entifier: DAS-
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Degradation of Microbial Binary PS149B1 Delta- Endotoxin in a Representative Soil from the Mid-Western USA Maize-Growing Region	45242214	68467	PER	
	Product durability plan for transgenic maize expressing insecticidal crystal protein from Bacillus thuringiensis strain PS149B1 during the experimental use period	45242215	68467	PER	
	Field efficacy of PS149B1 maize events against com rootworms	45242216	68467	PER	
	Microbial PS149B1 Binary Insecticidal Crystal Protein, Potlen Expressing PS149B1 Binary Insecticidal Crystal Protein, and Individual PS149B1 14kDa and 44 kDa Insecticidal Crystal Proteins	45340701	68467	PER	
	Thermolability of PS149B1 Binary Delta-Endotoxin	45358401	68467	PER	
	PS149B1binary insecticidal crystal protein: Acute toxicity study to the earthworm in an artificial substrate	45360201	68467	PER	
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date October 27, 2011	***************************************

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	DA	TA MATRIX				****
Date: October 27, 2011				EPA Reg. No.	/File Symbol: 68467-5	Page 57 of 66
Applicant's/Registrant's Name & Monsanto Company, 800 l	N. Lindbergh Blvd., St. Louis, MO 63167			Product: H	erculex® RW Insect P	
ngredient <i>B.t.</i> Cry34Ab1 a 59122-7)	nd Cry35Ab1 Insecticidal Crystal protein and the genetic n	naterial necessary t	for its production (plasmi	d insert PHP17	7662) in com (OECD Ide	ntifier: DAS-
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	2,000	Status	Note
	Lateral flow test kit method validation for the detection of the PS149B1 14 kDa and 44 kDa protein in maize grain	45383401	68467		PER	
	Heat lability of individual proteins of the PS149B4 binary ICP	45584501	68467		PER	
	In Vitro Simulated Gastrie Fluid Digestibility Study of Microbially Derived Cry34Ab1 Protein	45584502	68467		PER	
	Characterization of Cry34Ab1 and Cry35Ab1 from Recombinant Psetidonionas fluorescens and Transgenic Maize	45790401	68467		PER	
	Characterization of DNA Inserted into Transgenic Com Events (Cry34Ab1 and Cry35Ab1)	45790402	68467		PER	
	PS149B1 Binary Insecticidal Crystal Protein: An 8-Day Dietary Study with the Rainbow Tront, Oncorhynchus mykiss, Walbaum	45790403	68467		PER	7
	PS149B1 Binary Insecticidal Crystal Protein: An Acute Toxicity Study with the Daphnid, Daphnia magna Straus	45790404	68467		PER	
Signature	See Page 1 for Signature	20000 E	Name and Title J. Austin Burns, Ph.D Regulatory Affairs M	77	Date October 27, 2011	

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Date: October 27, 2011				EPA Reg. No./File Symbol: 68467-5	Page 58 of 66
	N. Lindbergh Blvd., St. Louis, MO 63167			Product: Herculex® RW Insect P	The state of the s
Ingredient B.t. Cry34Abl a 59122-7)	nd Cry35Ab1 Insecticidal Crystal protein and the genetic r	naterial necessary	for its production (plasmid	I insert PHP17662) in corn (OECD Ide	entifier: DAS-
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	PS149Bt Binary Insecticidal Crystal Protein: Dietary Toxicity to Parasitic Hymenoptera (Nasonia vitripennis)	45790405	68467	PER	
No	Assessment of Chronic Toxicity of Diet Containing Bacillus thuringiensis PS149B1 Insecticidal Crystal Protein to Collembnia (Folsomia candida)	45790406	68467	PER	
	PS t49Bt Insecticidal Crystat Protein: Dictary Toxicity to Green Lacewing Larvac (Chrysoperla carnea)	45790407	68467	PER	
	SDS-PAGE Sensitivity Analysis for Cry35Abt in Support of the Simulated Gastric Fluid Digestion Study MRID#45242212	45790408	68467	PER	
	Trait Durability and Experimental Use of Transgenic Maize Expressing the Insecticidal Crystalline Proteins Cry34Ab1 and Cry35Ab1	45790509	68467	PER	
	Field Efficacy of Cry34Ab1/Cry35Ab1 Maizc Events Against Com Rootworms	45790410	68467	PER	
No.	Product characterization data for Bocillus thuringiensis Cry34Abt and Cry35Abt proteins expressed in transgenic maize plants (PHP176581	45790501	68467	PER	
	Product Characterization Data for Bacillus thuringiensis Cry34Abt and Cry35Abt Proteins Expressed in Transgenic Maize Plants (PHP17662)	4579060t	68467	PER	
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Ma		

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Date: October 27, 2011	2002.000			EPA Reg. No./File Symbol: 68467-5	Page 59 of 66
	N. Lindbergh Blvd., St. Louis, MO 63167			Product: Herculex® RW Insect F	201000000000000000000000000000000000000
Ingredient B.t. Cry34AbI a 59122-7)	nd Cry35AbI Insecticidal Crystal protein and the genetic r	material necessary f	or its production (plasmid	l insert PHP17662) in com (OECD lde	entifier: DAS-
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Summary of Heat Lability Studies with Cry34Abt/Cry35Ab1	45808601	68467	PER	
	Quantitative ELISA analysis of Cry34Ab1 and Cry35Ab1 proteins expressed in maize plants transformed with the vector PHP17658	45833101	68467	PER	
	Quantitative ELISA analysis of Cry34Ab1 and Cry35Ab1 proteins expressed in maize plants transformed with the vector PHP17662	45833102	68467	PER	
	Quantitative ELISA Analysis of Cry34Ab1 and Cry35Ab1 Proteins Expressed in Maize Plants Transformed with the Vector PHP17662	45833201	68467		
	Slide Presentation Summarizing Cry34Ab1/Cry35Ab1 Heat Inactivation Studies.	45860201	68467	PER	
	Probe MOA studies to assess potential for protein synthesis inhibition by Bacillus thuringiensis PS149B1 Cry34Ab1/Cry35Ab1 proteins in rabbit reticulocyte assay; Re-examination of lab notebook data	45942801	68467	PER	
	Product characterization data for Bacillus thuringiensis Cry34Abt and Cry35Ab1 proteins expressed in transgenic maize plants (PHP1 7662)	46030001	68467	PER	
	Independent Laboratory Validation Pioneer Hi-Bred International, Inc. ELISA Method for the Quantitification of Cry34Ab1Protein from Transgenie Plants	46123901	68467	PER	
	Independent Laboratory Validation of Dow AgroSciences Method GRM 03.13, "Determination of Cry35Ab1 Insecticidal Crystal Protein in Maize Tissue by Enzyme- Linked Immunosorbent Assay"	46123902	68467	PER	The state of the s
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Ma		

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		TA MATRIX			<del></del>
Date: October 27, 2011		¥8	EF	A Reg. No./File Symbol: 68467-5	Page 60 of 66
	N. Lindbergh Blvd., St. Louis, MO 63167			oduct: Herculex® RW Insect Pr	
Ingredient <i>B.t.</i> Cry34Ab Las 59122-7)	nd Cry35Ab1 Insecticidal Crystal protein and the genetic r	material necessary t	for its production (plasmid in	sert PHP (7662) in corn (OECD 1der	itifier: DAS-
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Cry34/35 Protein Distribution and Familiarity	46123903	68467	PER	
	Agronomic Characteristics, Quantitative ELISA and Nutrient Composition Analysis of Hybrid Maize Lines Containing Cry34Ab1, Cry35Ab1 and PAT Genes: Chile Locations	46123904	68467	PER	
· · · · · · · · · · · · · · · · · · ·	Biological equivalency of Cry34/35Ab1 insecticidal erystal protein in transgenic plants and derived from transgenic Pseudomonas fluorescens	46123905	68467	PER	<u>,</u>
	Characterization of Cry34Ab1 and Cry35Ab1 Proteins Derived from Transgenic Maize event E4497.59, 1,22 (DAS-59122-7)	46123906	68467	PER	<u>-</u>
	Characterization of Phosophinothricin Acetyltransferase (PAT) Derived from Transgenic Maize Event E4497.59.1.22	46123907	68467	νer	
	Characterization of DNA Inserted into Transgenic Corn Events DAS-45216-6 and DAS-59122-7	46123908	68467	PER	
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manag	Date October 27, 2011	

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TO THE ORDER OF THE ORDER	on, DC 20460. Do not send the form to this address.	ATA MATRIX	***************************************		
		THE BUTCHINA			
Date: October 27, 2011				EPA Reg. No/File Symbol: 68467-5	Page 61 of 66
Applicant's/Registrant's Name &				NO DESCRIPTION OF THE PROPERTY	•
	N. Lindbergh Blvd., St. Louis, MO 63167			Product Herculex® RW Insect F	
59122-7) B.f. Cry34Ab1 a	nd Cry35Ab1 Insecticidal Crystal protein and the genetic i	malerial necessary 1	or its production (plasmic	nsert PHP17662) in com (OECD Ide	entifice: DAS-
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Detailed characterization of DNA inserted into transgenic corn events DAS-45216-6 and DAS-59122-7	46123909	68467	PER	
	Evaluation of microbe derived Cry34Ab1 and Cry35Ab1 proteins for protein synthesis inhibition activity	46123910	68467	PER	
	Nutritional Equivalency Study of Maize Containing Cry34Ab1 and Cry35AB1: Poultry Feeding Study	46123911	68467	PER	
	The effect of Cry34Ab1/Cry35Ab1 proteins on the development and moriality of the Ladybird beetle Colemegilia macrifata DeGeer	46123912	68467	PER	
	Non-target Invertebrate Ecological Risk Assessment for Field Corn Expressing Cry34Ab1 and Cry35Ab1 Insecticidal Crystal Proteins in Event DAS-591227	46123913	68467	PER	
	Evaluation of the impact of corn rootworm control strategies on non-target arthropods	46123914	68467	PER	
Signature	See Page 1 for Signature		Name and Title J. Auslin Burns, Ph.D. Regulatory Affairs Ma		

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	DA	TA MATRIX			
Date: October 27, 2011	20070	7 7 995,450	1	EPA Reg. No./File Symbol: 68467-5	Page 62 nf 66
Applicant's/Registrant's Name &					
	N. Lindbergh Blvd., St. Louis, MO 63167			Product: Herculex® RW Insect P	
Ingredient <i>B.t.</i> Cry34Ab1 a 59122-7)	nd Cry35Ab1 Inscencidal Crystal protein and the genetic r	naterial necessary I	for its production (plasmid i	insert PHP17662) in com (OECD Ide	nither: DAS-
Guideline Reference Number	Guideline Study Name	MRtD Number	Submitter	Status	Note
	Investigations into Dose of Cry34Ab1/Cry35Ab1 Rootworm-Resistant Maize Event DAS-59122-7 Against Western and northern Corn Rootworms in Support of Trait Durability Plans	46123915	68467	PER	
	Effect on Western Corn Rootworm Adults of Feeding on Cry34/35Ab1-Corn Rootworm Protected Corn Tissue and Implications for Product Durability	46123916	68467	PER	
A 899	Evaluation of endangered/threatened insect species relative to the use of Cry34Ab/Cry35Ab1 com rootworm-resistant maize hybrids	46123917	68467	PER	
	Trait Durability Plan for Cry34/35 Corn Rootworm Protected corn Event DAS-59122-7 Following Commercialization	46123918	68467	PER	
	Simulations of Corn Rootworm Adaptation to Cry34/35 Corn Rootworm Protected Corn in Support of Trait Durability Plans for Event DAS-59122-7	46123919	68467	PER	
	Digestion of Allergenic and Non-Allergenic Proteins in Simulated Gastric Fluid	46123920	68467	PER	
Signature	See Page 1 for Signature		Natue and Title J. Austin Burns, Ph.D. Regulatory Affairs Man	Date October 27, 2011 ager	

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	DA	TA MATRIX			
Date: October 27, 2011	100			EPA Reg. No./File Symbol: 68467-5	Page 63 of 66
	N. Lindbergh Blvd., St. Louis, MO 63167			Product Herculex® RW Insect P	
Ingrodient B.t. Cry34Abt a 59122-7)	nd Cry35Ab1 Insecticidal Crystal protein and the genetic r	naterial necessary I	for its production (plasmid	insert PHP17662) in com (OECD Idea	ntitier: DAS-
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Public Interest Document for Cry34/35Ab1 Corn Rootworm-Protected Corn	46123921	68467	PER	enge e
	Investigation of Potential Interaction between Cry1F and the Binary Cry34Ab1/Cry35Ab1 Proteins	46343806	68467	PER	
	Digestion efficiency of allergens and non-allergens in simulated gastric fluid: Bacillus tinuingiensis Cry 34/35Ab1 construct PHP17662	46388601	68467	PER	
	Lack of Cry34Ab1/Cry35Ab1 co-association in solution	46556801	68467	PER	
TO THE STATE OF TH	Evaluation of the Sequence Similarities of the Cry34Abl, cry35Abl, and PAT Proteins to the Public Protein Sequence Dalasets	46584701	68467	PER	
16.	Summary report of a carabid beetle laboratory toxicity study using Cry34Ab1 and Cry35Ab1 including copies of references	46714101	68467	PER	
Signature	See Page 1 for Signature		Name and Title J. Austin Bums, Ph.D. Regulatory Affairs Ma	1 100 000000000000000000000000000000000	

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	D/	ATA MATRIX			
Date: October 27, 2011				EPA Reg. No./File Symbol: 68467-5	Page 64 of 66
Applicant's/Registrant's Name & Monsanto Company, 800	Address: N. Lindbergh Blvd., St. Louis, MO 63167			Product: Herculex® RW Insect P	rotection
Ingredient B.t. Cry34Ab1 a 59122-7)	and Cry35Ab1 Insecticidal Crystal protein and the genetic	material necessary	for its production (plasmic	l insert PHP17662) in com (OECD Ide	ntifier: DAS-
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Preliminary resistance monitoring plan for Cry34/35Ab1 com event DAS-59122-7	46769201	68467	PER	
(MANAGE TO AND	Detailed resistance monitoring plan for Cry34/35Abl corn event DAS-59122-7	47334201	68467	PER	
	Evaluation of potential diesary effects of Cry34/35Ab1 protein on insidious flower bugs, Orius insidiosus (Hemiptera: Anthocoridae)	47436701	68467	per	
	Monitoring com rootworm susceptibility to Cry34/35Ab1 event DAS-59122-7: 2007 insect collections	47522501	68467	PER	
	Three-Year Field Monitoring of Cry34/35Ab1 and Cry1F x Cry34/35Ab1 Maize Hybrids for Nontarget Arthropod Effects	4787030 t	68467	PER	
330	Monitoring corn rootworm suscentibility to Cry34/35Abl event DAS-59122-7: 2008 insect collections	47900801	68467	PER	
Signature	See Page 1 for Signature	207	Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Ma	or the control of the	

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	<u>D</u> /	ATA MATRIX			
Date: October 27, 2011			EPA F	Reg. No./File Symbol: 68467-5	Page 65 of 66
	N. Lindbergh Blvd., St. Louis, MO 63167			et: Herculex® RW <i>Insect P</i>	
Ingredient B.t. Cry34Ab1 a 59122-7)	and Cry35Ab1 Insecticidal Crystal protein and the genetic	material necessary t	for its production (plasmid inscrt	PHPt7662) in com (OECD Ide	entifier: DAS-
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Soil accumulation of Cry34Ab1 and Cry35Ab1 proteins after three years of cropping with DAS-59122-7 corn	47959501	68467	PER	
	Investigating Performance of Herculex <sup>TM</sup> RW and Herculex <sup>TM</sup> XTRA Under Commercial Use	48045501	68467	PER	
	Monitoring Com Rootworm Susceptibility to Cry34/35Ab1 Event DAS-59122-7: 2009 Growing Season	48279701	68467	PER	
	2010 Insect Resislance Management Compliance Assurance Program for Corn Borer Protected Bt Corn, Corn Rootworn Protected Bt Corn, and Corn Borer/Corn Rootworn-Protected Stacked Bt Corn	4837500 t	68467	PER	
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date October 27, 2011	

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401 M Street, S.W., Washington	n, DC 20460. Do not send the form to this address.			Designation	
		ATA MATRIX			
Date: October 27, 2011				EPA Reg. No./File Symbol: 68467-5	Page 66 of 66
	. Lindbergh Blvd., St. Louis, MO 63167			Product: Herculex® RW Insect	
Ingredient B.r. Cry34Ab1 and 59122-7)	d Cry35Ab1 Insecticidal Crystal protein and the genetic	material necessary f	or its production (plasmic	d insert PHP17662) in corn (OECD I	dentifier: DAS-
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Enhanced Insect Resistance Management Compliance Assurance Program for Com Borer Protected Bt Com, Com Rootworm Protected Bt Com, and Com Borer/Com Rootworm-Protected Stacked Bt Com	4837510t	68467	PER	
	Revised Guidelines for Evaluating Unexpected Corn Rootworm Damage in Herculex® RW and Herculex® XTRA	48 <u>43070</u> I	68467	PER	
			2		
				20	
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Ma	anagcr	
EPA Form 8570-35 (9-97) Electro	onic and Paper versions available. Submit only Paper vers	sion.		Agency I	iternal Use Copy

## SUMMARY OF THE APPLICATION

The subject of this application is for the registration extension of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 Insect Protected, Herbicide-Tolerant Corn (Genuity® SmartStax® RIB Complete™; EPA Reg. No. 524-595).

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ was conditionally registered on April 8, 2011. The initial time-limited registration expired on October 31, 2011, which was subsequently extended to November 30, 2011. This current application request is to extend EPA Reg. No. 524-595 for a period of two years beyond the current November, 30, 2011 expiration date based on the EPA's registration decision in the BRAD for this product (EPA Docket ID EPA-HQ-OPP-2011-0362-0002, April 8, 2011; p27). An updated data matrix is being supplied with this application. With the exception of the revised label to incorporate bag-tag language suitable for both the corn- and cotton-growing areas as required under the current terms and conditions, no other changes are being requested to the registration conditions as part of this registration extension request.

RIB Complete is a trademark of Monsanto Technology, LLC.

<sup>&</sup>lt;sup>®</sup> Genuity and SmartStax are registered trademarks of Monsanto Technology LLC.

### PRODUCT LABEL

The subject of this application is for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>TM</sup>. No substantive changes to the label for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 Insect-Protected, Herbicide-Tolerant Corn in EPA Reg. No. 524-595, as updated April 8, 2011, are being requested. The patent numbers have been updated. Five copies of the proposed label for the registration of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>TM</sup> are attached.

## Plant-Incorporated Protectant Label

## MON 89034 × TC1507 × MON 88017 × DAS-59122-7

RIB Complete<sup>TM</sup>
Insect-Protected, Herbicide-Tolerant Corn
(Alternate Brand Name: Genuity® SmartStax® RIB Complete<sup>TM</sup>)‡
(OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-1 ×
MON-88Ø17-3 × DAS-59122-7)

MON-00017-3 ^ DA3-39122-7)
Active Ingredients:
Bacillus thuringiensis Cry1A.105 protein and the genetic material (vector PV-ZMIR245)
necessary for its production in corn event MON 89034 (OECD Unique Identifier: MON-89Ø34-3)
≤0.0026%*
D 'H (1 - 1 - 1 C) 2.412 mass.
Bacillus thuringiensis Cry2Ab2 protein and the genetic material (vector PV-ZMIR245)
necessary for its production in corn event MON 89034 (OECD Unique Identifier: MON-89034-3)
≤0.0053%*
Bacillus thuringiensis Cry1F protein and the genetic material (vector PHP8999) necessary
for its production in corn event TC1507 (OECD Unique Identifier: DAS- Ø15Ø7-1) \( \leq 0.0012\% \)
Tot its production in corn every a crown (OLOD Single Identific). DAS- 21327-1) 0.001270
Bacillus thuringiensis Cry3Bb1 protein and the genetic material (vector PV-ZMIR39)
necessary for its production in corn event MON 88017 (OECD Unique Identifier: MON-88Ø17-3)
≤0.0079%*
Bacillus thuringiensis Cry34Ab1 protein and the genetic material (vector PHP17662)
necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7)
≤0.0194%*
Bacillus thuringiensis Cry35Abl protein and the genetic material (vector PHP17662)
necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7)
≤ 0.0042%*
Other Ingredients:
CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) and the genetic material
(vector PV-ZMIR39) necessary for its production in corn event MON 88017
≤0.0052%*
PAT protein (phosphinothricin acetyl transferase) and the genetic material (vectors
PHP17662 and PHP8999) necessary for its production in corn events TC1507 and
DAS-59122-7≤0.00045%*
*Maximum percent (wt/wt) of dry forage
‡ Genuity® SmartStax® RIB Complete™ seed with this refuge configuration contains 95%
MON 89034 $\times$ TC1507 $\times$ MON 88017 $\times$ DAS-59122-7 mixed with at least 5% non-Bt corn
within a single lot of seed.

### KEEP OUT OF REACH OF CHILDREN

## **CAUTION**

NET CONTENTS\_\_\_\_

EPA Registration No. 524-595 EPA Establishment No. 524-MO-002

Monsanto Company 800 North Lindbergh Blvd. St. Louis, MO 63167

### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. This product must be used as specified in the terms and conditions of the registration.

This product may be combined or produced through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>TM</sup> protects corn crops from leaf, stalk, and ear damage caused by lepidopteran corn pests listed on this label and root damage caused by corn rootworm larvae listed on this label. In order to minimize the risk of these pests developing resistance to MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>TM</sup> corn, an insect resistance management plan must be implemented as defined in the registration terms and conditions.

Grower agreements will specify that growers must adhere to the refuge requirements that will be described on the bag or bag/tag for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>TM</sup> corn or other applicable product use documents.

Sales of corn hybrids that contain Monsanto's Bt corn plant-incorporated pesticide(s) must be accompanied by either an IRM/Grower Guide or information on the bag or bag-tag, on planting, production, and insect resistance management, and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the Bt proteins is planted.

Corn seed bags or bag tags for products containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>TM</sup> must include the refuge size requirement in text and graphical format.

### INSECT RESISTANCE MANAGEMENT

Growers are instructed to read information on insect resistance management in the bag and/or bag-tag.

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per plant-incorporated protectant (PIP) active ingredient per registrant per year.

The seed producer must ensure a minimum of 5% non-PIP refuge seed is included with the MON  $89034 \times TC1507 \times MON 88017 \times DAS-59122-7$  in each lot of seed corn. The refuge seed in the seed mixture may not be treated with seed-applied insecticides for corn rootworm (CRW) control unless the MON  $89034 \times TC1507 \times MON 88017 \times DAS-59122-7$  seed in the seed mixture receives the same treatment.

The IRM/Grower Guide for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>TM</sup> or comparable information presented on the product bag or bag-tag, must contain the following information:

This product is a seed mixture containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 and a minimum of 5% non-Bt seed that when planted creates an interspersed refuge within the field. There are no requirements for a separate structured refuge for Genuity<sup>®</sup> SmartStax<sup>®</sup> RIB Complete<sup>TM</sup> corn when planted in the U.S. corn-growing region, including Alaska and Hawaii, because the refuge seed is contained within the bag/container.

The interspersed refuge can only be used by planting seed corn specifically generated by qualified seed producers/conditioners licensed by the registrant. Insecticidal treatments labeled for adult CRW control are discouraged during the time of adult CRW emergence.

The seed mix refuge option for Genuity<sup>®</sup> SmartStax<sup>®</sup> RIB Complete<sup>TM</sup> satisfies the refuge requirements in all regions other than in the cotton-growing region where corn earworm is a significant pest as defined below.

# Additional refuge requirements in the cotton-growing region where corn carworm is a significant pest

In the cotton-growing region where corn earworm is a significant pest, as defined below, Genuity<sup>®</sup> SmartStax<sup>®</sup> RIB Complete<sup>TM</sup> requires the planting of an additional 20% structured refuge (i.e. 20 acres of non-Bt corn for every 80 acres of Genuity<sup>®</sup> SmartStax<sup>®</sup> RIB Complete<sup>TM</sup> planted).

The 20% refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn rootworms or corn borers. The refuge and the Genuity<sup>®</sup> SmartStax<sup>®</sup> RIB Complete<sup>TM</sup> should be sown on the same day, or with the shortest window possible between

planting dates to ensure that corn root development is similar among varieties. The structured refuge may be planted as an in-field or adjacent (e.g., across the road) refuge or planted as a separate block that is within ½ mile of the Genuity SmartStax RIB Complete<sup>TM</sup> field. In-field refuge options include blocks, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The refuge can be protected from lepidopteran damage by use of non-Bt insecticides if the population of one or more target lepidopteran pests of Genuity SmartStax RIB Complete<sup>TM</sup> in the refuge exceeds economic thresholds. In addition, the refuge can be protected from CRW damage by an appropriate seed treatment or soil insecticide; however, insecticides labeled for adult CRW control must be avoided in the refuge during the period of CRW adult emergence. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants).

The cotton-growing region requiring the additional 20% refuge consists of the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).

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## Corn Insects Controlled or Suppressed

European corn borer (ECB)
Southwestern corn borer (SWCB)
Southern cornstalk borer (SCSB)
Corn earworm (CEW)
Fall armyworm (FAW)
Stalk borer
Lesser corn stalk borer
Sugarcane borer (SCB)
Western bean cutworm (WBC)
Black cutworm

Western corn rootworm (WCRW)
Northern corn rootworm (NCRW)

Mexican corn rootworm (MCRW)

Ostrinia nubilalis
Diatraea grandiosella
Diatraea crambidoides
Helicoverpa zea
Spodoptera frugiperda
Papaipema nebris
Elasmopalpus lignosellus
Diatraea saccharalis
Richia albicosta
Agrotis ipsilon

Diabrotica virgifera virgifera Diabrotica barberi Diabrotica virgifera zeae

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 is a product of Monsanto's and Dow AgroSciences' research programs, offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents: 5322938, 5352605, 5359142, 5378619, 5424412, 5550318, 5554798, 5641876, 5717084, 5728925, 5804425, 6018100, 6025545, 6051753, 6063597, 6083878, 6331665, 6489542, 6645497, 6713063, 6962705, 7064249, 7070982, 7112665, 7227056, 7250501, 7304206, 7544862, 7618942, 7927598, and RE39247.

EPA Accepted: \_\_/\_/\_

## Plant-Incorporated Protectant Label

## MON 89034 × TC1507 × MON 88017 × DAS-59122-7

RIB Complete<sup>TM</sup>
Insect-Protected, Herbicide-Tolerant Corn
(Alternate Brand Name: Genuity® SmartStax® RIB Complete<sup>TM</sup>)‡
(OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7)

NOT-66917-3 ~ DAG-39122-1)
Active Ingredients:  Bacillus thuringiensis Cry1A.105 protein and the genetic material (vector PV-ZMIR245) necessary for its production in corn event MON 89034 (OECD Unique Identifier: MON-89034-3)
≤ 0.0026%*
Bacillus thuringiensis Cry2Ab2 protein and the genetic material (vector PV-ZMIR245) necessary for its production in corn event MON 89034 (OECD Unique Identifier: MON-89034-3)
≤0.0053%*
Bacillus thuringiensis Cry1F protein and the genetic material (vector PHP8999) necessary
for its production in corn event TC1507 (OECD Unique Identifier: DAS-Ø15Ø7-1)≤ 0.0012%*
Bacillus thuringiensis Cry3Bb1 protein and the genetic material (vector PV-ZMIR39)
necessary for its production in corn event MON 88017 (OECD Unique Identifier: MON-88017-3)
≤0.0079%*
Bacillus thuringiensis Cry34Ab1 protein and the genetic material (vector PHP17662)
necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7)
≤ 0.0194%*
Bacillus thuringiensis Cry35Abl protein and the genetic material (vector PHP17662)
necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7)
≤ 0.0042%*
Other Ingredients:
CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) and the genetic material (vector PV-ZMIR39) necessary for its production in corn event MON 88017
≤0.0052%*
PAT protein (phosphinothricin acetyl transferase) and the genetic material (vectors
PHP17662 and PHP8999) necessary for its production in corn events TC1507 and
DAS-59122-7≤0.00045%*
*Maximum percent (wt/wt) of dry forage
to the second se
‡ Genuity® SmartStax® RIB Complete <sup>TM</sup> seed with this refuge configuration contains 95% MON 89034 × TC1507 × MON 88017 × DAS-59122-7 mixed with at least 5% non- <i>Bt</i> corn within a single lot of seed.

### KEEP OUT OF REACH OF CHILDREN

## CAUTION

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EPA Registration No. 524-595 EPA Establishment No. 524-MO-002

Monsanto Company 800 North Lindbergh Blvd. St. Louis, MO 63167

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It is a violation of Federal law to use this product in any manner inconsistent with its labeling. This product must be used as specified in the terms and conditions of the registration.

This product may be combined or produced through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>TM</sup> protects corn crops from leaf, stalk, and ear damage caused by lepidopteran corn pests listed on this label and root damage caused by corn rootworm larvae listed on this label. In order to minimize the risk of these pests developing resistance to MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>TM</sup> corn, an insect resistance management plan must be implemented as defined in the registration terms and conditions.

Grower agreements will specify that growers must adhere to the refuge requirements that will be described on the bag or bag/tag for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ corn or other applicable product use documents.

Sales of corn hybrids that contain Monsanto's Bt corn plant-incorporated pesticide(s) must be accompanied by either an IRM/Grower Guide or information on the bag or bag-tag, on planting, production, and insect resistance management, and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the Bt proteins is planted.

Corn seed bags or bag tags for products containing MON 89034 × TCI 507 × MON 88017 × DAS-59122-7 RIB Complete<sup>TM</sup> must include the refuge size requirement in text and graphical format.

### INSECT RESISTANCE MANAGEMENT

Growers are instructed to read information on insect resistance management in the bag and/or bag-tag.

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per plant-incorporated protectant (PIP) active ingredient per registrant per year.

The seed producer must ensure a minimum of 5% non-PIP refuge seed is included with the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 in each lot of seed corn. The refuge seed in the seed mixture may not be treated with seed-applied insecticides for corn rootworm (CRW) control unless the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 seed in the seed mixture receives the same treatment.

The IRM/Grower Guide for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>TM</sup> or comparable information presented on the product bag or bag-tag, must contain the following information:

This product is a seed mixture containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 and a minimum of 5% non-Bt seed that when planted creates an interspersed refuge within the field. There are no requirements for a separate structured refuge for Genuity® SmartStax® RIB Complete<sup>TM</sup> corn when planted in the U.S. corn-growing region, including Alaska and Hawaii, because the refuge seed is contained within the bag/container.

The interspersed refuge can only be used by planting seed corn specifically generated by qualified seed producers/conditioners licensed by the registrant. Insecticidal treatments labeled for adult CRW control are discouraged during the time of adult CRW emergence.

The seed mix refuge option for Genuity<sup>®</sup> SmartStax<sup>®</sup> RIB Complete<sup>™</sup> satisfies the refuge requirements in all regions other than in the cotton-growing region where corn earworm is a significant pest as defined below.

## Additional refuge requirements in the cotton-growing region where corn earworm is a significant pest

In the cotton-growing region where corn earworm is a significant pest, as defined below, Genuity® SmartStax® RIB Complete™ requires the planting of an additional 20% structured refuge (i.e. 20 acres of non-Bt corn for every 80 acres of Genuity® SmartStax® RIB Complete™ planted).

The 20% refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn rootworms or corn borers. The refuge and the Genuity<sup>®</sup> SmartStax<sup>®</sup> RIB Complete<sup>TM</sup> should be sown on the same day, or with the shortest window possible between

Monsanto Company 11-CR-192E-2R Page 93 of 110

planting dates to ensure that corn root development is similar among varieties. The structured refuge may be planted as an in-field or adjacent (e.g., across the road) refuge or planted as a separate block that is within ½ mile of the Genuity® SmartStax® RIB Complete<sup>TM</sup> field. In-field refuge options include blocks, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The refuge can be protected from lepidopteran damage by use of non-Bt insecticides if the population of one or more target lepidopteran pests of Genuity® SmartStax® RIB Complete<sup>TM</sup> in the refuge exceeds economic thresholds. In addition, the refuge can be protected from CRW damage by an appropriate seed treatment or soil insecticide; however, insecticides labeled for adult CRW control must be avoided in the refuge during the period of CRW adult emergence. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants).

The cotton-growing region requiring the additional 20% refuge consists of the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).

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## Corn Insects Controlled or Suppressed

European corn borer (ECB)
Southwestern corn borer (SWCB)
Southern cornstalk borer (SCSB)
Corn earworm (CEW)
Fall armyworm (FAW)
Stalk borer
Lesser corn stalk borer
Sugarcane borer (SCB)
Western bean cutworm (WBC)
Black cutworm

Western corn rootworm (WCRW) Northern corn rootworm (NCRW) Mexican corn rootworm (MCRW) Ostrinia nubilalis
Diatraea grandiosella
Diatraea crambidoides
Helicoverpa zea
Spodoptera frugiperda
Papaipema nebris
Elasmopalpus lignosellus
Diatraea saccharalis
Richia albicosta
Agrotis ipsilon

Diabrotica virgifera virgifera Diabrotica barberi Diabrotica virgifera zeae

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 is a product of Monsanto's and Dow AgroSciences' research programs, offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents: 5322938, 5352605, 5359142, 5378619, 5424412, 5550318, 5554798, 5641876, 5717084, 5728925, 5804425, 6018100, 6025545, 6051753, 6063597, 6083878, 6331665, 6489542, 6645497, 6713063, 6962705, 7064249, 7070982, 7112665, 7227056, 7250501, 7304206, 7544862, 7618942, 7927598, and RE39247.

EPA Accepted: \_\_/\_/\_

## Plant-Incorporated Protectant Label

## MON 89034 × TC1507 × MON 88017 × DAS-59122-7

RIB Complete<sup>TM</sup>
Insect-Protected, Herbicide-Tolerant Corn
(Alternate Brand Name: Genuity® SmartStax® RIB Complete<sup>TM</sup>)‡
(OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-1 ×
MON-88Ø17-3 × DAS-59122-7)

1101-000113 - 1010-37122 - 1
Active Ingredients:  Bacillus thuringiensis Cry1A.105 protein and the genetic material (vector PV-ZMIR245)  necessary for its production in corn event MON 89034 (OECD Unique Identifier: MON-89Ø34-3)
Bacillus thuringiensis Cry2Ab2 protein and the genetic material (vector PV-ZMIR245) necessary for its production in corn event MON 89034 (OECD Unique Identifier: MON-89Ø34-3)
Bacillus thuringiensis Cry1F protein and the genetic material (vector PHP8999) necessary for its production in corn event TC1507 (OECD Unique Identifier: DAS- Ø15Ø7-1)≤ 0.0012%*
Bacillus thuringiensis Cry3Bb1 protein and the genetic material (vector PV-ZMIR39) necessary for its production in corn event MON 88017 (OECD Unique Identifier: MON-88Ø17-3) ≤ 0.0079%*
Bacillus thuringiensis Cry34Ab1 protein and the genetic material (vector PHP17662) necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7) ≤ 0.0194%*
Bacillus thuringiensis Cry35Ab1 protein and the genetic material (vector PHP17662) necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7)≤ 0.0042%*
Other Ingredients: CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) and the genetic material (vector PV-ZMIR39) necessary for its production in corn event MON 88017
PAT protein (phosphinothricin acetyl transferase) and the genetic material (vectors PHP17662 and PHP8999) necessary for its production in corn events TC1507 and DAS-59122-7≤0.00045%*
*Maximum percent (wt/wt) of dry forage
‡ Genuity® SmartStax® RIB Complete™ seed with this refuge configuration contains 95% MON 89034 × TC1507 × MON 88017 × DAS-59122-7 mixed with at least 5% non-Bt corn within a single lot of seed.

### KEEP OUT OF REACH OF CHILDREN

## CAUTION

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EPA Registration No. 524-595 EPA Establishment No. 524-MO-002

Monsanto Company 800 North Lindbergh Blvd. St. Louis, MO 63167

## **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. This product must be used as specified in the terms and conditions of the registration.

This product may be combined or produced through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>TM</sup> protects corn crops from leaf, stalk, and ear damage caused by lepidopteran corn pests listed on this label and root damage caused by corn rootworm larvae listed on this label. In order to minimize the risk of these pests developing resistance to MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>TM</sup> corn, an insect resistance management plan must be implemented as defined in the registration terms and conditions.

Grower agreements will specify that growers must adhere to the refuge requirements that will be described on the bag or bag/tag for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>TM</sup> corn or other applicable product use documents.

Sales of corn hybrids that contain Monsanto's Bt corn plant-incorporated pesticide(s) must be accompanied by either an IRM/Grower Guide or information on the bag or bag-tag, on planting, production, and insect resistance management, and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the Bt proteins is planted.

Corn seed bags or bag tags for products containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>TM</sup> must include the refuge size requirement in text and graphical format.

### INSECT RESISTANCE MANAGEMENT

Growers are instructed to read information on insect resistance management in the bag and/or bag-tag.

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per plant-incorporated protectant (PIP) active ingredient per registrant per year.

The seed producer must ensure a minimum of 5% non-PIP refuge seed is included with the MON  $89034 \times TC1507 \times MON~88017 \times DAS-59122-7$  in each lot of seed corn. The refuge seed in the seed mixture may not be treated with seed-applied insecticides for corn rootworm (CRW) control unless the MON  $89034 \times TC1507 \times MON~88017 \times DAS-59122-7$  seed in the seed mixture receives the same treatment.

The IRM/Grower Guide for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>TM</sup> or comparable information presented on the product bag or bag-tag, must contain the following information:

This product is a seed mixture containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 and a minimum of 5% non-Bt seed that when planted creates an interspersed refuge within the field. There are no requirements for a separate structured refuge for Genuity<sup>®</sup> SmartStax<sup>®</sup> RIB Complete<sup>TM</sup> corn when planted in the U.S. corn-growing region, including Alaska and Hawaii, because the refuge seed is contained within the bag/container.

The interspersed refuge can only be used by planting seed corn specifically generated by qualified seed producers/conditioners licensed by the registrant. Insecticidal treatments labeled for adult CRW control are discouraged during the time of adult CRW emergence.

The seed mix refuge option for Genuity<sup>®</sup> SmartStax<sup>®</sup> RIB Complete<sup>TM</sup> satisfies the refuge requirements in all regions other than in the cotton-growing region where corn earworm is a significant pest as defined below.

## Additional refuge requirements in the cotton-growing region where corn earworm is a significant pest

In the cotton-growing region where corn earworm is a significant pest, as defined below, Genuity® SmartStax® RIB Complete™ requires the planting of an additional 20% structured refuge (i.e. 20 acres of non-Bt corn for every 80 acres of Genuity® SmartStax® RIB Complete™ planted).

The 20% refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn rootworms or corn borers. The refuge and the Genuity<sup>®</sup> SmartStax<sup>®</sup> RIB Complete<sup>TM</sup> should be sown on the same day, or with the shortest window possible between

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planting dates to ensure that corn root development is similar among varieties. The structured refuge may be planted as an in-field or adjacent (e.g., across the road) refuge or planted as a separate block that is within ½ mile of the Genuity® SmartStax® RIB Complete™ field. In-field refuge options include blocks, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The refuge can be protected from lepidopteran damage by use of non-Bt insecticides if the population of one or more target lepidopteran pests of Genuity® SmartStax® RIB Complete™ in the refuge exceeds economic thresholds. In addition, the refuge can be protected from CRW damage by an appropriate seed treatment or soil insecticide; however, insecticides labeled for adult CRW control must be avoided in the refuge during the period of CRW adult emergence. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants).

The cotton-growing region requiring the additional 20% refuge consists of the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).

### Corn Insects Controlled or Suppressed

European corn borer (ECB)
Southwestern corn borer (SWCB)
Southern cornstalk borer (SCSB)
Corn earworm (CEW)
Fall armyworm (FAW)
Stalk borer
Lesser corn stalk borer

Sugarcane borer (SCB)
Western bean cuttworm (WI

Western bean cutworm (WBC)

Black cutworm

Western corn rootworm (WCRW) Northern corn rootworm (NCRW) Mexican corn rootworm (MCRW) Ostrinia nubilalis
Diatraea grandiosella
Diatraea crambidoides
Helicoverpa zea
Spodoptera frugiperda
Papaipema nebris
Elasmopalpus lignosellus
Diatraea saccharalis
Richia albicosta
Agrotis ipsilon

Diabrotica virgifera virgifera Diabrotica barberi Diabrotica virgifera zeae

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 is a product of Monsanto's and Dow AgroSciences' research programs, offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents: 5322938, 5352605, 5359142, 5378619, 5424412, 5550318, 5554798, 5641876, 5717084, 5728925, 5804425, 6018100, 6025545, 6051753, 6063597, 6083878, 6331665, 6489542, 6645497, 6713063, 6962705, 7064249, 7070982, 7112665, 7227056, 7250501, 7304206, 7544862, 7618942, 7927598, and RE39247.

EPA Accepted: \_\_/\_/\_

### Plant-Incorporated Protectant Label

## MON 89034 × TC1507 × MON 88017 × DAS-59122-7

RIB Complete<sup>TM</sup>
Insect-Protected, Herbicide-Tolerant Corn
(Alternate Brand Name: Genuity® SmartStax® RIB Complete<sup>TM</sup>)‡
(OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-1 ×
MON-88Ø17-3 × DAS-59122-7)

Active Ingredients:
Bacillus thuringiensis Cry1A.105 protein and the genetic material (vector PV-ZMIR245) necessary for its production in corn event MON 89034 (OECD Unique Identifier: MON-89Ø34-3)  \$\leq 0.0026\%*\$
Bacillus thuringiensis Cry2Ab2 protein and the genetic material (vector PV-ZMIR245) necessary for its production in corn event MON 89034 (OECD Unique Identifier: MON-89Ø34-3)
Bacillus thuringiensis Cry1F protein and the genetic material (vector PHP8999) necessary for its production in corn event TC1507 (OECD Unique Identifier: DAS- Ø15Ø7-1)≤ 0.0012%*
Bacillus thuringiensis Cry3Bb1 protein and the genetic material (vector PV-ZMIR39) necessary for its production in corn event MON 88017 (OECD Unique Identifier: MON-88Ø17-3) ≤ 0.0079%*
Bacillus thuringiensis Cry34Ab1 protein and the genetic material (vector PHP17662) necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7) ≤ 0.0194%*
Bacillus thuringiensis Cry35Ab1 protein and the genetic material (vector PHP17662) necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7) ≤ 0.0042%*
Other Ingredients: CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) and the genetic material (vector PV-ZMIR39) necessary for its production in corn event MON 88017≤0.0052%*
PAT protein (phosphinothricin acetyl transferase) and the genetic material (vectors PHP17662 and PHP8999) necessary for its production in corn events TC1507 and DAS-59122-7≤0.00045%*
*Maximum percent (wt/wt) of dry forage
‡ Genuity® SmartStax® RIB Complete™ seed with this refuge configuration contains 95% MON 89034 × TC1507 × MON 88017 × DAS-59122-7 mixed with at least 5% non-Bt corn within a single lot of seed.

### KEEP OUT OF REACH OF CHILDREN

## CAUTION

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EPA Registration No. 524-595 EPA Establishment No. 524-MO-002

Monsanto Company 800 North Lindbergh Blvd. St. Louis, MO 63167

### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. This product must be used as specified in the terms and conditions of the registration.

This product may be combined or produced through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred com lines and hybrid corn varieties with combined pesticidal traits.

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>TM</sup> protects com crops from leaf, stalk, and ear damage caused by lepidopteran corn pests listed on this label and root damage caused by corn rootworm larvae listed on this label. In order to minimize the risk of these pests developing resistance to MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>TM</sup> corn, an insect resistance management plan must be implemented as defined in the registration terms and conditions.

Grower agreements will specify that growers must adhere to the refuge requirements that will be described on the bag or bag/tag for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>TM</sup> corn or other applicable product use documents.

Sales of corn hybrids that contain Monsanto's Bt corn plant-incorporated pesticide(s) must be accompanied by either an IRM/Grower Guide or information on the bag or bag-tag, on planting, production, and insect resistance management, and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the Bt proteins is planted.

Corn seed bags or bag tags for products containing MON  $89034 \times TC1507 \times MON 88017 \times DAS-59122-7$  RIB Complete<sup>TM</sup> must include the refuge size requirement in text and graphical format.

#### INSECT RESISTANCE MANAGEMENT

Growers are instructed to read information on insect resistance management in the bag and/or bag-tag.

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per plant-incorporated protectant (PIP) active ingredient per registrant per year.

The seed producer must ensure a minimum of 5% non-PIP refuge seed is included with the MON  $89034 \times TC1507 \times MON~88017 \times DAS-59122-7$  in each lot of seed corn. The refuge seed in the seed mixture may not be treated with seed-applied insecticides for corn rootworm (CRW) control unless the MON  $89034 \times TC1507 \times MON~88017 \times DAS-59122-7$  seed in the seed mixture receives the same treatment.

The IRM/Grower Guide for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>TM</sup> or comparable information presented on the product bag or bag-tag, must contain the following information:

This product is a seed mixture containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 and a minimum of 5% non-Bt seed that when planted creates an interspersed refuge within the field. There are no requirements for a separate structured refuge for Genuity<sup>®</sup> SmartStax<sup>®</sup> RIB Complete<sup>TM</sup> corn when planted in the U.S. corn-growing region, including Alaska and Hawaii, because the refuge seed is contained within the bag/container.

The interspersed refuge can only be used by planting seed corn specifically generated by qualified seed producers/conditioners licensed by the registrant. Insecticidal treatments labeled for adult CRW control are discouraged during the time of adult CRW emergence.

The seed mix refuge option for Genuity<sup>®</sup> SmartStax<sup>®</sup> RIB Complete<sup>TM</sup> satisfies the refuge requirements in all regions other than in the cotton-growing region where corn earworm is a significant pest as defined below.

# Additional refuge requirements in the cotton-growing region where corn earworm is a significant pest

In the cotton-growing region where corn earworm is a significant pest, as defined below, Genuity<sup>®</sup> SmartStax<sup>®</sup> RIB Complete<sup>TM</sup> requires the planting of an additional 20% structured refuge (i.e. 20 acres of non-Bt corn for every 80 acres of Genuity<sup>®</sup> SmartStax<sup>®</sup> RIB Complete<sup>TM</sup> planted).

The 20% refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn rootworms or corn borers. The refuge and the Genuity® SmartStax® RIB Complete<sup>TM</sup> should be sown on the same day, or with the shortest window possible between

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planting dates to ensure that corn root development is similar among varieties. The structured refuge may be planted as an in-field or adjacent (e.g., across the road) refuge or planted as a separate block that is within ½ mile of the Genuity® SmartStax® RIB Complete<sup>TM</sup> field. In-field refuge options include blocks, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The refuge can be protected from lepidopteran damage by use of non-Bt insecticides if the population of one or more target lepidopteran pests of Genuity® SmartStax® RIB Complete<sup>TM</sup> in the refuge exceeds economic thresholds. In addition, the refuge can be protected from CRW damage by an appropriate seed treatment or soil insecticide; however, insecticides labeled for adult CRW control must be avoided in the refuge during the period of CRW adult emergence. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants).

The cotton-growing region requiring the additional 20% refuge consists of the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).

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### Corn Insects Controlled or Suppressed

European corn borer (ECB)
Southwestern corn borer (SWCB)
Southern cornstalk borer (SCSB)
Corn earworm (CEW)
Fall armyworm (FAW)
Stalk borer
Lesser corn stalk borer
Sugarcane borer (SCB)
Western bean cutworm (WBC)
Black cutworm

Western corn rootworm (WCRW) Northern corn rootworm (NCRW) Mexican corn rootworm (MCRW) Ostrinia nubilalis
Diatraea grandiosella
Diatraea crambidoides
Helicoverpa zea
Spodoptera frugiperda
Papaipema nebris
Elasmopalpus lignosellus
Diatraea saccharalis
Richia albicosta
Agrotis ipsilon

Diabrotica virgifera virgifera Diabrotica barberi Diabrotica virgifera zeae

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 is a product of Monsanto's and Dow AgroSciences' research programs, offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents: 5322938, 5352605, 5359142, 5378619, 5424412, 5550318, 5554798, 5641876, 5717084, 5728925, 5804425, 6018100, 6025545, 6051753, 6063597, 6083878, 6331665, 6489542, 6645497, 6713063, 6962705, 7064249, 7070982, 7112665, 7227056, 7250501, 7304206, 7544862, 7618942, 7927598, and RE39247.

EPA Accepted: \_\_/\_\_/\_\_

### Plant-Incorporated Protectant Label

### MON 89034 × TC1507 × MON 88017 × DAS-59122-7

RIB Complete<sup>TM</sup>
Insect-Protected, Herbicide-Tolerant Corn
(Alternate Brand Name: Genuity® SmartStax® RIB Complete<sup>TM</sup>)‡
(OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7)

Active Ingredients

Bacillus thuringiensis Cryl A.105 protein and the genetic material (vector PV-ZMIR245) necessary for its production in corn event MON 89034 (OECD Unique Identifier: MON-89Ø34-3)
Bacillus thuringiensis Cry2Ab2 protein and the genetic material (vector PV-ZMIR245) necessary for its production in corn event MON 89034 (OECD Unique Identifier: MON-89034-3)≤ 0.0053%*
Bacillus thuringiensis Cry1F protein and the genetic material (vector PHP8999) necessary for its production in corn event TC1507 (OECD Unique Identifier: DAS- Ø15Ø7-1)≤ 0.0012%*
Bacillus thuringiensis Cry3Bb1 protein and the genetic material (vector PV-ZMIR39) necessary for its production in corn event MON 88017 (OECD Unique Identifier: MON-88Ø17-3) ≤ 0.0079%*
Bacillus thuringiensis Cry34Ab1 protein and the genetic material (vector PHP17662) necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7) ≤ 0.0194%*
Bacillus thuringiensis Cry35Ab1 protein and the genetic material (vector PHP17662) necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7) ≤ 0.0042%*
Other Ingredients: CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) and the genetic material (vector PV-ZMIR39) necessary for its production in corn event MON 88017  \$\leq 0.0052\%**
PAT protein (phosphinothricin acetyl transferase) and the genetic material (vectors PHP17662 and PHP8999) necessary for its production in corn events TC1507 and DAS-59122-7
‡ Genuity® SmartStax® RIB Complete™ seed with this refuge configuration contains 95% MON 89034 × TC1507 × MON 88017 × DAS-59122-7 mixed with at least 5% non-Bt corn within a single lot of seed.

#### KEEP OUT OF REACH OF CHILDREN

### CAUTION

1

NET CONTENTS\_\_\_\_

EPA Registration No. 524-595 EPA Establishment No. 524-MO-002

Monsanto Company 800 North Lindbergh Blvd. St. Louis, MO 63167

### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. This product must be used as specified in the terms and conditions of the registration.

This product may be combined or produced through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>TM</sup> protects corn crops from leaf, stalk, and ear damage caused by lepidopteran corn pests listed on this label and root damage caused by corn rootworm larvae listed on this label. In order to minimize the risk of these pests developing resistance to MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>TM</sup> corn, an insect resistance management plan must be implemented as defined in the registration terms and conditions.

Grower agreements will specify that growers must adhere to the refuge requirements that will be described on the bag or bag/tag for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>TM</sup> com or other applicable product use documents.

Sales of corn hybrids that contain Monsanto's Bt corn plant-incorporated pesticide(s) must be accompanied by either an IRM/Grower Guide or information on the bag or bag-tag, on planting, production, and insect resistance management, and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the Bt proteins is planted.

Corn seed bags or bag tags for products containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>TM</sup> must include the refuge size requirement in text and graphical format.

#### INSECT RESISTANCE MANAGEMENT

Growers are instructed to read information on insect resistance management in the bag and/or bag-tag.

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per plant-incorporated protectant (PIP) active ingredient per registrant per year.

The seed producer must ensure a minimum of 5% non-PIP refuge seed is included with the MON  $89034 \times TC1507 \times MON$   $88017 \times DAS-59122-7$  in each lot of seed com. The refuge seed in the seed mixture may not be treated with seed-applied insecticides for com rootworm (CRW) control unless the MON  $89034 \times TC1507 \times MON$   $88017 \times DAS-59122-7$  seed in the seed mixture receives the same treatment.

The IRM/Grower Guide for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>TM</sup> or comparable information presented on the product bag or bag-tag, must contain the following information:

This product is a seed mixture containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 and a minimum of 5% non-Bt seed that when planted creates an interspersed refuge within the field. There are no requirements for a separate structured refuge for Genuity<sup>®</sup> SmartStax<sup>®</sup> RIB Complete<sup>TM</sup> corn when planted in the U.S. corn-growing region, including Alaska and Hawaii, because the refuge seed is contained within the bag/container.

The interspersed refuge can only be used by planting seed corn specifically generated by qualified seed producers/conditioners licensed by the registrant. Insecticidal treatments labeled for adult CRW control are discouraged during the time of adult CRW emergence.

The seed mix refuge option for Genuity<sup>®</sup> SmartStax<sup>®</sup> RIB Complete<sup>TM</sup> satisfies the refuge requirements in all regions other than in the cotton-growing region where corn earworm is a significant pest as defined below.

# Additional refuge requirements in the cotton-growing region where corn earworm is a significant pest

In the cotton-growing region where corn earworm is a significant pest, as defined below, Genuity<sup>®</sup> SmartStax<sup>®</sup> RIB Complete<sup>TM</sup> requires the planting of an additional 20% structured refuge (i.e. 20 acres of non-Bt corn for every 80 acres of Genuity<sup>®</sup> SmartStax<sup>®</sup> RIB Complete<sup>TM</sup> planted).

The 20% refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn rootworms or corn borers. The refuge and the Genuity<sup>®</sup> SmartStax<sup>®</sup> RIB Complete<sup>™</sup> should be sown on the same day, or with the shortest window possible between

Monsanto Company 11-CR-192E-2R Page 108 of 110

planting dates to ensure that corn root development is similar among varieties. The structured refuge may be planted as an in-field or adjacent (e.g., across the road) refuge or planted as a separate block that is within ½ mile of the Genuity® SmartStax® RIB Complete<sup>TM</sup> field. In-field refuge options include blocks, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The refuge can be protected from lepidopteran damage by use of non-Bt insecticides if the population of one or more target lepidopteran pests of Genuity® SmartStax® RIB Complete<sup>TM</sup> in the refuge exceeds economic thresholds. In addition, the refuge can be protected from CRW damage by an appropriate seed treatment or soil insecticide; however, insecticides labeled for adult CRW control must be avoided in the refuge during the period of CRW adult emergence. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants).

The cotton-growing region requiring the additional 20% refuge consists of the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).

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### Corn Insects Controlled or Suppressed

European corn borer (ECB) Southwestern corn borer (SWCB) Southern cornstalk borer (SCSB)

Corn earworm (CEW) Fall armyworm (FAW)

Stalk borer

Lesser corn stalk borer Sugarcane borer (SCB)

Western bean cutworm (WBC)

Black cutworm

Western corn rootworm (WCRW) Northern corn rootworm (NCRW)

Mexican corn rootworm (MCRW)

Ostrinia nubilalis
Diatraea grandiosella
Diatraea crambidoides
Helicoverpa zea
Spodoptera frugiperda
Papaipema nebris
Elasmopalpus lignosellus
Diatraea saccharalis

Diatraea sacchar Richia albicosta Agrotis ipsilon

Diabrotica virgifera virgifera

Diabrotica barberi

Diabrotica virgifera zeae

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 is a product of Monsanto's and Dow AgroSciences' research programs, offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents: 5322938, 5352605, 5359142, 5378619, 5424412, 5550318, 5554798, 5641876, 5717084, 5728925, 5804425, 6018100, 6025545, 6051753, 6063597, 6083878, 6331665, 6489542, 6645497, 6713063, 6962705, 7064249, 7070982, 7112665, 7227056, 7250501, 7304206, 7544862, 7618942, 7927598, and RE39247.

EPA Accepted: \_\_/\_\_/\_

# 

Pages 118-128 - \* Claimed confidential by submitter\*



J. Austin Burns Regulatory Affairs Manager (314) 694-6514

June 10, 2011

MONSANTO COMPANY 800 NORTH LINDBERGH BLVO ST. LOUIS, MISSOUBI 63137 http://www.monsanto.com

Document Processing Desk (PETN)
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7511P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attn: Dr. Sheryl Reilly, Team Leader 92

Subject: Application to extend the registration of MON 89034 × TC1507 × MON 88017 ×

DAS-59122-7 RIB Complete™; EPA Registration Number 524-595; non-PRIA.

Dear Dr. Reilly:

Please find an application for the registration extension of the plant-incorporated protectant MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>™</sup> Insect Protected, Herbicide-Tolerant Corn (EPA Reg. No. 524-595) enclosed.

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>TM</sup> was conditionally registered on April 8, 2011. The initial time-limited registration expires on October 31, 2011. During the initial registration period, Monsanto, in conjunction with Dow AgroSciences (EPA Reg. No. 68467-16), are providing further information supporting this product in accordance with the terms and conditions of registration, including an updated draft label. This current application request is to extend EPA Reg. No. 524-595 for a period of two years beyond the current expiration date based on the EPA's registration decision in the BRAD for this product (EPA Docket ID EPA-HQ-OPP-2011-0362-0002, April 8, 2011; p27). A subsequent registration extension will be requested at that time, based on the revised registration duration scheme for PIP products representing reduced risk for developing insect resistance (Optimum® AcreMax™ B.t. Corn Seed Blends BRAD; August 4, 2010; p19). An updated data matrix is being supplied with this application. With the exception of the revised label to incorporate bag-tag language suitable for both the corn- and cotton-growing areas as required under the current terms and conditions, no other changes are being made to the registration conditions as part of this registration extension request, and a timely review and decision is therefore requested.

<sup>™</sup> RIB Complete is a trademark of Monsanto Technology LLC

Pursuant to this request, attached is a letter from Dow AgroSciences authorizing data citation related to Events TC1507 and DAS-59122-7.

The documents accompanying this submission are listed in the table below. The table includes the classification categories "A", "B", and "C" for each document, as defined by the Agency:

- Category "A": Materials that can be released to anyone, regardless of affiliation to a foreign or multi-national pesticide producer.
- Category "B": Information can be released only to individuals that attest they are not employees or agents of a foreign or multi-national pesticide producer, as per FIFRA Section 10(g).
- Category "C": Confidential Business Information that is protected from any disclosure indefinitely by provisions put forth by the EPA, as per FIFRA Section 10.

A CD-ROM containing the fully releasable ("A") documents, with the exception of the data citation authorization letter, is provided in .pdf format.

It is Monsanto's understanding that this request is a non-PRIA action.

• Fee category: Non-PRIA Amendment

• Fee category amount: \$0

Documents accompanying this application for registration

Volume	Category	Document	Hard copy	.pdf file for E-docket
N/A	A	Cover letter	√	
N/A	A	Dow AgroSciences data citation letter	√	
N/A	A	Transmittal document	√	√
1	В	Administrative Materials for the Application to Amend the Registration of the Plant-Incorporated Protectant, Bacillus thuringiensis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, With an Interspersed In-Field Refuge Configuration Using a Seed Mixture	√	
1	С	Confidential Statement of Formula	V	

Should you require any additional information regarding this application please feel free to contact Daniel Jenkins at 202-383-2851, or myself at 314-694-6514.

Sincerely,

J. Austin Burns, Ph.D.

Regulatory Affairs Manager

Monsanto Company

cc: Mike Mendelson, EPA/OPP/BPPD Russell Schneider, Monsanto Nicholas Storer, Dow AgroSciences Stephanie Burton, Dow AgroSciences Dow AgroSciences, LLC 9330 Zionsville Road Indianapolis, IN 46268-1054



May 27, 2011

Document Processing Desk Office of Pesticide Programs (7504P) U.S. Environmental Protection Agency Room S-4900, One Potomac Yard 2777 South Crystal Drive Arlington, VA 22202-4501

Attn: Dr. Keith Matthews, Esq., Director Biopesticide and Pollution Prevention Division

#### LETTER AUTHORIZING DATA CITATION

We hereby confirm that Agrigenetics, Inc. d/b/a Mycogen Seeds c/o Dow AgroSciences LLC, on behalf of itself and its affiliates, (collectively, "Dow AgroSciences") authorizes Monsanto Company (Monsanto) to cite, and the U.S. Environmental Protection Agency (EPA) to refer to, data previously submitted by Dow AgroSciences in connection with any of the following products:

- Insect-protected, glufosinate-tolerant maize containing the Cry1F and PAT proteins, Event TC1507 (DAS-01507-1);
- Insect-protected, glufosinate-talerant maize containing the Cry34/35Ab1 and PAT proteins, Event DAS-59122-7 (DAS-59122-7)

and all relevant data that Dow AgroSciences has provided EPA to support the Section 3 registration extension for MON 89034 x TC1507 x MON 88017 x DAS-59122-7 Insect-Protected, Herbicide-Tolerant Corn (Refuge Advanced™ Powered by SmartStax® / Genuity® SmartStax® RIB Complete™), EPA Registration Nos. 68467-16 and 524-595.

This authorization shall not be construed as authorization to use or consider said data, directly or indirectly, in support of any application submitted by any other applicant, for an application by Monsanto for activities other than the registration request as described herein, or for any other regulatory entity to refer to or rely on this data. Dow AgroSciences does not grant permission for citation or reference of this data for any use not specifically stated herein, does not grant permission for citation or reference of data (including future data) not specified herein, and nothing in this agreement grants permission for the U.S. EPA to provide copies of any data to any party.

If you require further information, please contact the undersigned at 317-337-3692.

Best Regards.

Gregory L. Orr, Ph.D.

Global Regulatory Leader - Corn Traits

Dow AgroSciences LLC

Dryng low



### TRANSMITTAL DOCUMENT

#### SUBMITTED BY

Monsanto Company 800 N. Lindbergh Blvd. St. Louis, MO 63167

# REGULATORY ACTION IN SUPPORT OF WHICH THIS DOCUMENT IS SUBMITTED

Administrative Materials for the Application to Amend the Registration of the Plant-Incorporated Protectant, Bacillus thuringiensis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, With an Interspersed In-Field Refuge Configuration Using a Seed Mixture

EPA Registration Number: 524-595

#### TRANSMITTAL DATE

June 10, 2011

#### MONSANTO REFERENCE No.

11-CR-192E-2R

Monsanto Company 11-CR-192E-2R Page 1 of 2 133

### LIST OF SUBMITTED DOCUMENTS

### Administrative Materials

Volume 1. Administrative Materials for the Application to Amend the Registration of the Plant-Incorporated Protectant, *Bacillus thuringiensis* Cryl A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, With an Interspersed In-Field Refuge Configuration Using a Seed Mixture

MRID	Number		
Company Official:	J. Austin Burns, Ph.D. Regulatory Affairs Manager (314) 694-6514	6-10-2011 Date	_
Company Name:	Monsanto Company		
Company Contact:	Daniel Jenkins, J.D., M.S. U.S. Agency Regulatory Affairs Manager		

(202) 383-2851.

Monsanto Company 11-CR-192E-2R Page 2 of 2 134

1 3 3 1 3

\* 1 1 1 1 1

Ms. Stephanie Burton Associate Biotech Regulatory Manager Mycogen Seeds c/o Dow AgroSciences LLC 9330 Zionsville Road Indianapolis, Indiana 46268-1054

Subject: Refuge Advanced™ Powered by SmartStax®
June 1, 2011 Application to Amend the Expiration Date
EPA Registration Nos. 68467-16

Dear Ms. Burton:

The amendment referred to above, submitted in connection with registration under Section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable provided that the revised expiration date for this product is November 30, 2011. Per our discussions with Dow AgroSciences, the Agency intends to determine a longer term expiration date for this product, along with other SmartStax related products, during the month of November. In order to facilitate this process, please submit a corresponding amendment application.

Sincerely,

Sheryl K. Reilly, Ph.D. Chief, Microbial Pesticides Branch Biopesticides and Pollution Prevention Division (7511P)



#### VOLUME 1

Administrative Materials for the Application to Amend the Plant-Incorporated Protectant, Bacillus thuringiensis Cryl A.105, Cry2Ab2, CrylF, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, With an Interspersed In-Field Refuge Configuration Using a Seed Mixture

EPA Reg. Number: 524-595

#### **AUTHORS**

Bradley A. Comstock J. Austin Burns, Ph.D.

### SUBMISSION DATE

June 10, 2011

#### SUBMITTING REGISTRANT

Monsanto Company 800 N. Lindbergh Blvd. St. Louis, MO 63167

#### MONSANTO REFERENCE No.

11-CR-192E-2R

The text below applies only to use of the data by the United States Environmental Protection Agency (U.S. EPA) in connection with the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

### STATEMENT OF DATA CONFIDENTIALITY CLAIM

No claim of data confidentiality is being made for information contained in this document on the basis of its falling within the scope of FIFRA §10(d)(1)(A), (B), or (C). However, a supplemental data confidentiality claim is being made for some information claimed herein. The applicable information has been removed to a confidential attachment.

"We submit this material to the United States Environmental Protection Agency specifically under requirements set forth in FIFRA as amended, and consent to use and disclosure of this material by the EPA strictly in accordance with FIFRA. By submitting this material to EPA in accordance with the method and format requirements contained in PR Notice 86-5, we reserve and do not waive any rights involving this material that are or can be claimed by the company notwithstanding this submission to the EPA."

COMPANY:

Monsanto Company

COMPANY AGENT:

Austin Burns, Ph.D.

Regulatory Affairs Manager

DATE:

June 10, 2011

### GLP COMPLIANCE STATEMENT

The materials in this volume do not meet the requirements of the Good Laboratory Practice Standards, 40 CFR Part 160. This volume provides the administrative materials for the Application to amend the registration of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 Insect Protected, Herbicide-Tolerant Corn with an interspersed in-field refuge configuration using a seed mixture, and therefore were not developed in compliance with 40 CFR Part 160.

//	an
	Submitter
	J. Austin Burns, Ph.D.
	Regulatory Affairs Manager

T - 1 /	6-10-11
Sponsor	Date
Jeffrey T. Bookout, M.S., M.B.A.	
Corn Regulatory Affairs Lead	

Study Director Date

Bradley A. Comstock

Regulatory Affairs Manager

6-10-2011 Date

### **VOLUME 1**

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Please read instructions on reverse b	efore completing form.		Form Approved,	OMB No. 207	70-0060. A	pproval Expire	es 2-28-95
<b>⊕</b> EPA	<b>Environmer</b> Was	United States  1tal Protect Shington, DC 2	ction Agend	<b>y</b>		egistratior Amendmen Other	Number
	Applica	tion for P	esticide – S	Section I			· · · · · · · · · · · · · · · · · · ·
Company/Product Number     File Sym	ibol 524-595		2. EPA Produc	Un 1980	eilly	3. Pr	roposed Classification
Company/Product (Name) MON 89034 × TC1507 × N	MON 88017 × DAS	-59122-7	PM#	92			None Restricted
5. Name and Address of Applicant (In Monsanto Company 800 North Lindbergh Blvd. St. Louis, MO 63167  Check if this is a new address	clude ZtP Code)		6. Expedited product is similar EPA Reg. No.	ar or identical	in composi	tion and labeli	···
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524-595		Secti	on – III				
1. Material This Product Will Be Pallild-Resistant Packaging  Yes*  No  * Certification must be submitted	Unit Packaging Yes No	No. per - Container	Water Soluble Pa	No. per Container		ype of Contain Metal Plastic Glass Paper Other	ner
Location of Net Contents Information     Label	1	4. Size(s) Reta	Il Container Various		5. Locatio		ections panying product
6. Manner in Which Label is Affixed to	Product	Lithograp Paper glu Stenciled	ed	Other			
Contact Point (Complete Items direct	tly below for identification	Maria de la companya della companya	on – IV	necessary lo	process thi	is application	
Name Daniel J. Jenkins,		Title	gency Regula			Telephone Code)	No. (Include Area 2) 383-2851
t certify that the statements I have t acknowledge that any knowingly both under applicable law.	made on this form and						6. Date Application Received (Stamped)
2. Signature / MM		3. Title	Regulatory A	Affairs Mar	ager		(otambeu)
Typed Name		5. Date					

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete.

Tel. (314) 694-6514

White - EPA File Copy (original) Yellow Applicant Copy 11-CR-192E-2R

Monsanto Company

J. Austin Burns, Ph.D.

June 10, 2011

### CONFIDENTIAL STATEMENT OF FORMULA

{CBI Cross Reference Number 1}

Monsanto Company 11-CR-192E-2R Pages 6 to 16 of 410

### **SEPA**

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S. W. WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC, 20460. Do not send the completed form to this address.

Environmental Protection Agency, 401 W. Street, B.W., Wash	agion DC, 2000. Do not s	end the completed form to take address.
Certification with I	Respect to Citation of	Data
Applicant's/Registrant's Name, Address, and Telephone Number: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, (314) 694-6514	MO 63167	EPA Registration Number / File Symbol: 524-595
Active Ingredient(s) and/or representative lest compound(s): Bacil Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1 and Cry35Ab1 Proteins and the Ge ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Produ × MON 88017 × DAS-59122-7	enetic Materials (Vectors PV-	Date: June 1 <b>0</b> , 2011
General Use Pattern(s) (list all those claimed for this product using 40	CFR Part 158:	Product Name:
Terrestrial field crop		MON 89034 × TCt507 × MON 88017 × DAS-59122- 7 RIB Complete <sup>FM</sup>
NOTE: If your product is a 100% repackaging of another purchased need to submit this form. You must submit the Formulator's Exemption		
I am responding to a Data-Call-in Notice, and have included w should be used for this purpose).	ith this form a list of companies	sent offers of compensation (the Data Matrix form
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I am using the cite-all method of support, and have included we this form a list of companies sent offers of compensation (the Data Matrix Form should be used for this purpose).	the selective me	elective method of support (or cite-all option under sthod), and have included with this form a f data requirements (the Data Matrix form must be
Section II: GEI	NERAL OFFER TO PA	Y
[Required if using the cite-all method or when using the cite-al	l option under the selective me	thod to satisfy one or more data requirements)
I hereby offer and agree to pay compensation, to other person	is, with regard to the approval of	of this application, to the extent required by FIFRA.
Section III	: CERTIFICATION	
I certify that this application for registration, this form for reregist the application for registration, the form for registration, or the Data-Cal method is indicated in Section 1, this application is supported by all dat an identical or substantially similar product, one or more of the ingredie under the data requirements in effect on the date of approval of this application and uses.	I-In response. In addition, if the a in the Agency's files that (1) on the in this product; and (2) is a	e cite-alt option or cite-all option under the selective concern the properties or effects of this product or type of data that would be required to be submitted
I certify that for each exclusive use study cited in support of this registre the written permission of the original data submitter to cite that study.	ation or reregistration, that I am	the original data submitter or that I have obtained
I certify that for each study cited in support of this registration or re submitter; (b) I have obtained the permission of the original data sub- compensation have expired for the study; (d) the study is in the public have offered (i) to pay compensation to the extent required by secti- determine the amount and terms of compensation, if any, to be paid for	nitter to use the study in suppo : literature; (e) I have notified ir ons 3(c)(1)(F) and/or 3(c)(2)(E	ort of this application; (c) all periods of eligibility for a writing the company that submitted the study and
I certify that in all instances where an offer of compensation is require accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are avaisuch evidence to the Agency upon request, I understand that the Agency of conformity with FIFRA.	lable and will be submitted to the	ne Agency upon request. Should I fail to produce
I certify that the statements I have made on this form and all attacknowingly false of misleading statement may be punishable by fin		
Signature /	Date	Typed or Printed Name and Title
y. an	June 10, 2011	J. Austin Bums, Ph.D. Regulatory Affairs Manager
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DATA MATRIX Date: June 1, 2011 EPA Reg. No./File Symbol: 524-595 Page I of 66 Applicant's/Registrant's Name & Address: Product: MON 89034 × TC1507 × Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167 MON 88017 × DAS-59122-7 RIB Complete™ Ingredient Bacillus thuringiensis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MDN 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89034-3 × DAS-01507-1 × MON-88017-3 × DAS-59122-7) MRID Number Guideline Reference Number Guideline Sludy Name Submitter Status Note Administrative Materials for the Application to Amend the Plant-Incorporated Protectant. Bacillus thuringionsis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Crv35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, With an Interspersed In-Administrative Field Refuge Configuration Using a Seed Mixture OWN This Submission Monsanto Company Administrative Materials for Dow AgroSciences' and Monsanto's Response to Uncertainties Raised by the SmartStax® RIB Scientific Advisory Panel, Dec 8-9. Administrative 484234-00 OWN Monsanto Contpany Supporting Data NA Dow AgroSciences' and Monsanto's Response to Uncertainties Raised by the SmartStax® RIB Scientific Supporting Data NA Advisory Paucl, Dec 8-9, 2010. 484234-01 OWN Monsanto Company Monsanto Protocol/Refuge Assurance Program, including Licensee Seed Conditioner's Qualification for Seed Mix NA Refuge Products (RIB) 48394001 Monsanto Company OWN Supporting Data Information Regarding the Manufacturing Process for a 5% Seed Mix Refuge for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (Genuity® SmartStax®; EPA File NA Symbol 524-LOL) N/A Monsanto Company OWN Supporting Data Name and Title Date Signature SIGNATURE PAGE FOR 66 PAGES J. Austin Burns, Ph.D. June 1, 2011 Regulatory Affairs Manager

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Monsanto Company

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DATA MATRIX						
Date: June 1, 2011	EPA Reg. No./File Symbol: 524-595	Page 2 of 66				
Applicant's/Registrant's Name & Address:	Product: MON 89034 × TC	1507 ×				
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	MON 88017 × DAS-59122-7 RIB (	MON 88017 × DAS-59122-7 RIB Complete™				

Ingredient Bacillus rhuringiensis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
NA	Administrative Materials for the Application to Register the Plant-Incorporated Protectant, Bacillus thuringiensis Cryl A. 105, Cry2Ab2, Cryl F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, With an Interspersed In-Field Refuge Configuration Using a Seed Mixture	47943700	Monsanto Company	OWN	Administrative
NA NA	Five Percent Seed Mix Refuge as an Insect Resistance Management Option for MON 89034 × TC1507 × MON 88017 × DAS-59122-7	47943701	Monsanto Company	OWN	Supporting Data
NA	The Benefits of a 5% Interspersed In-field Refuge Option for SmartStax™ Com	47943702	Monsanto Company	OWN	Benefits
Signature See Page 1 for Signature			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date June 1, 2011	

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Date: June I, 2011			EPA	Reg. No./File Symbol: 524-581	Page 3 of 66
Applicant's/Rogistrant's Name & Address:  Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167				oduct: MON 89034 × TC1507 : DAS-59122-7	19000000000000000000000000000000000000
	nsis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, a r their Production in MON 89034 × TC1507 × MON 8801				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Goodwin, B.K., Marra, M.C., and N.E. Piggott. 2009.  Farm-Level Benefits of a Refuge Reduction for SmartStax Tal. A report from Agri-Analytics, Inc.	N/A	Monsaato Company	OWN	Supporting Information
	Burns, J.A. 2009. The Benefits of Refuge Reduction to 5% for SmartStax Com	47943702	Monsamo Company	OWN	Supporting Information
	Burns, J.A. 2009. Response to U.S. EPA BPPD Letter, Dated March 19, 2009 Regarding Applications to Register MON 89034 ×TC1507 × MON 88017 × DAS-59122-7 EPA file Symbols: 524-LIR (MON); D-395123 (DAS).	N/A	Monsanio Company	OWN	Supporting Information
	Bogdanova, N., J.A. Bums, G. Head, et. at. 2009. Condition of Registration for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 Insect-protected and Herbieide Tolerant Com: Compliance Assurance Plan	47883601	Monsanto Company	OWN	Terms and Conditions
	Bogdanova, N., J. Cardea, J. Lambert, et. al. 2009. Educational Materials and Information of IRM Requirements Provided by Monsanto Company to Growers of MON 89034 × TC 1507 × MON 88017 × DAS-59122-7 Insect-protected and Herbicide Tolerant Com	47883602	Monsanto Company	own	Terms and Conditions
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manage	Date June 1, 2011	

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	D/	ATA MATRIX			
Date: June 1, 2011			E	PA Reg. No./File Symbol: 524-581	Page 4 of 66
Applicant's/Registrant's Name & Monsanto Company, 800 l	Address: N. Lindbergh Blvd., St. Louis, MO 63167			Product: MON 89034 × TC1507 DAS-59122-7	× MON 88017 ×
	ensis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, or their Production in MON 89034 × TC1507 × MON 880				
Guideline Reference Number	Guideline Study Name	MRtD Number	Sabmitter	Statns	Note
	Head, G., W. Moar, and N. Storer, 2009. Insect Resistance Monitoring and a Remedial Action Plan for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 Insect-protected and Herbicide Tolerant Corn	47883603	Monsauto Compan	y OWN	Terms and Conditions
	Keller, P. 2011. Annual Sales Report for MON 810, MON 863, MON 863 × MON 810, MON 88017, MON 88017 × MON 810, MON 89034, MON 88017 × MON 89034, and MON 88017 × MON 89034 × TC1507 × DAS-59122-7	48367801	Monsanto Compan	y OWN	Terms and Conditions
	Submission of Pesticide Use Data in Support of the Registrations of MON 810, MON 863, MON 863 × MON 810, MON 88017, MON 88017 × MON 810, MON 89034 (× NK603), MON 89034 × MON 88017, MON 89034 × TC1507 × MON 88017 × DAS-59122-7	48367800	Monsanto Compan	y OWN	Terms and Conditions
	Zahora, A. and P. Keller. 2011. 2010 Insect Resistance Management Compliance Assurance Program Report for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 Insect-protected and Herbicitle Tolerant Com	48367901	Mousanto Compan	y OWN	IRM

48369700

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DAS-59122-7

Submission of Efficacy Data in Support of the Registration of MON 89034 × TC1507 × MON 88017 ×

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OWN

Date

June 1, 2011

Signature

Monsanto Company

Name and Title

J. Austin Burns, Ph.D. Regulatory Affairs Manager Product

Characterization

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	D/	TA MATRIX				
Date: June 1, 2011				EPA Reg. No./Fi	lc Symbol: 524-581	Page 5 of 66
Applicant's/Registrant's Name & Monsanto Company, 800 }		Product: MON 89034 × TC1507 × MON 88017 × DAS-59122-7				
	nsis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, a r their Production in MON 89034 × TC1507 × MON 8801					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter		Status	Note
	Head, G., M. Carroll, L. Stork, et. al. 2011. Com Rootworm Adult Emergence from MON 89034 × TC1507 × MON 88017 × DAS-59122-7, MON 88017, DAS-59122-7, and Non-Bt Corn with Various Egg Densities in 2010 U.S. Field Trials	48369701	Monsanto Com	pany	OWN	IRM
595562 5751 (Mill)	Administrative Materials for the Application to Register the Plant-Incorporated Protectant, Bacillus thuringiensis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34 and Cry35 Proteins and the Genetic Materials (Vectors PVZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7.		Monsanto Cont	pany	own	Administrative
885.1100	Burns, J.A. 2008. Human Health and Environmental Assessment of the Plant-Incorporated Protectant Byreillas thuringiensis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins Produced in the Combined Trait Com Product MON 89034 × TCt 507 × MON 88017 × DAS-59122-7. Monsanto Technical Report MSL0021223.	47444901	Monsanto Com	pany	OWN	Product Characterization
885.1100	Ricc, J.F. 2008. Summary of Southern Blot Analyses to Confirm the Presence of MON 89034, TC1507, MON 88017, and DAS-59122-7 in the Combined Trait Com Product MON 89034 × TC1507 × MON 88017 × DAS- 59122-7. Monsanto Technical Report MSL0021265.	47444902	Monsanto Com		OWN	Product Claracterization
885.1100	Taylor, J.P., J.R Groat, and J.D. Masucci. 2007. Southern Blot Analyses to Confirm the Presence of MON 89034 and MON 88017 in the Combined Trait Com Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Monsauto Technical Report MSL0020682.	47444903	Monsanto Con	parry	OWN	Product Characterization
Signature	See Page I for Sig⊓ature		Name and Title J. Austin Burns, Ph.D Regulatory Affairs M	. ] ]	Dale une 1, 2011	3979 V

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	DA	TA MATRIX		and the second s		
Date: June 1, 2011				EPA Reg. No./File Symbol: 524-58	Page 6 of 66	
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167				Product: MON 89034 × TC1507 × MON 88017 × DAS-59122-7		
	nsis Cryl A. 105, Cry2 Ab2, Cry1 F, Cry3 Bb1, Cry3 4 Ab1, a r their Production in MON 89034 × TC1507 × MON 8801					
Guideline Reference Number	Guideline Study Name	MRfD Number	Submitter	Slatus	Note	
885.1100	Schater, B.W., C.Q. Cia, and S.K. Embrey. 2008. Southern Blot Analyses to Confirm the Presence of TC1507 and DAS-59122-7 in the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Dow AgroSciences Study ID 071179.	47444904	Monsanto Com	pany OWN	Product Characterization	
885.1100	Murphy, J.A. and J.S. McClain. 2008. Summary of Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, CP4 EPSPS, Cry34Ab1, Cry35Ab1 and PAT Protein Levels in the Combined Trait Com Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7 Produced in US Field Trials in 2006. Monsanto Teclmical Report MSL0021266.	47444905	Monsanto Com	pany OWN	Product Characterization	
885.1100	Stillwell, L. and A. Silvanovich. 2007. Assessment of Cryl A. 105, Cry2 Ab2, Cry3 Bb1, and CP4 EPSPS Protein Levels in the Combined Trait Com Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Monsanto Technical Report MSL0021070.	47444906	Monsanto Con	pany OWN	Production Characterization	
885.1100	Phillips, A.M. 2008. Cry34Ab1, Cry35Ab1, Cry1F, and PAT Protein Levels in Hybrid Maize TC1507, DAS-59122-7, MON 89034 × TC1507 × MON 88017 × DAS-59122-7, and a Conventional Control from the Monsanto 2006 Production Plan 06-01-52-04. Dow AgroSciences Study 1D 061026.06.	47444907	Monsanto Com	pany OWN	Product Characterization	
N/A	Levine, S. 2008. Studies Performed to Evaluate the Potential for Interactions among Cry Proteins Produced by MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Monsanto Technical Report MSL0021267.	47444908	Monsanto Com	pany OWN	Environmental Assessment	
Signature	See Page 1 for Signature	·	Name and Title J. Austin Burns, Ph.D Regulatory Affairs Ma			

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The Participant Control	DA	TA MATRIX		SCOOKS SECTION CONTRACTOR OF	50-33-00g 50 00-00-00
Dute: June 1, 2011				EPA Reg. No./File Symbol: 524-581	Page 7 of 66
	N. Lindbergh Blvd., St. Louis, MO 63167		20000000	Product: MON 89034 × TC150 DAS-59122-7	
Ingredient Bacillus thuringle and PHP17662) Necessary fo DAS-59122-7)	msis Cry1A, 105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, a r Their Production in MON 89034 × TC1507 × MON 8801	nd Cry35Ab1 Prot 7 × DAS-59122-7	eins and the Genetic Mate (OECD Unique Identifier:	rials (Vectors PV-ZMIR245, PHP89 : MON-89034-3 × DAS-01507-1 >	999, PV-ZMIR39, 4 MON-88Ø17-3×
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	MacRae, T. 2008. Evaluation of Potential for Interaction Between the <i>Bacillus illuringiensis</i> Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins. Monsanto Technical Report MSL0020554.	47444909	Monsanto Comp	oanyOWN	Environmental Assessment
N/A	Levine, S. 2008. Evaluation of the Potential for Interactions among Cry Proteins Produced by MON 89034 × TC1507 × MON 88017 × DAS-59122-7 by Insect Bioassay. Monsanto Technical Report MSL0021104.	47444910	Monsanto Comp	oany OWN	Environmental Assessment
N/A	Head, G. and N. Storer. 2008. Insect Resistance Management Plan for MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Monsanto Technical Report MSL0021285.	47444911	Monsanto Comp	oany OWN	IRM
N/A	Levine, S. and J. Huesing. 2008. Endangered Species Impact Assessment for the Combined Trail Com Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Monsanto Technical Report MSL0021268.	47444912	Monsanto Conq	Dany OWN	Environmental Assessment
885.4340	Paradise, M. 2008. Evaluation of Potential Dictary Effects of Pollen From the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7 on the Ladybird Beetle Coleomegilla maculata (Coleoptern: Coecinellidae). Monsanto Technical Report MSL 0021036.	47444913	Monsanto Comp	pany OWN	Environmental Assessment
Signature	See Page 1 for Signature	20 20 40 240 32	Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Ma		

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	DA	ATA MATRIX			
Date: June 1, 2011		EPA	Reg. No./File Symbol: 524-575	Page 8 of 66	
Applicant's/Registrant's Name & Monsanto Company, 800 Monsanto Education Bacillus thuring	Address: V. Lindbergh Blvd., St. Louis, MO 63167 iensis Cry I A. 105 and Cry2Ab2 Proteins and the Genetic N	Astorial (Ventor DV		Production in MON 89034 (OF	°D Unique
Identifier: MON-89034-3)	ensis Cryta. 103 and Cryzabz (Totellis and the Genetic is	raterial ( vector 1 v	-SMITTE 437 Necessary for men	170dilchoj) jij MO14 89034 (OEC	
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Updated Compliance Assurance Plan, Educational Materials, tRM Monitoring, and a Remedial Action Plan for MON 89034 (BPA Reg. No. 524-575) and MON 89034 × MON 88017 (EPA Reg. No. 524-576) Insect-Protected and Herbicide-Tolerant Com	483696-01	Monsanto Company	OWN	Terms & Conditions
	Annual Sales Report for MON 810, MDN 863, MON,863 × MON 810, MON 88017, MON 88017 × MON 810, MON 89034, MON 88017 × MON 89034, and MON 88017 × MON 89034 × TC1507 × DAS-59122-7 (EPA Reg. Nos. 524-489, 524-528, 524-545, 524-551, 524-552, 524-575, 524-576, and 524-581)	483678-0 <b>1</b>	Monsanto Company	own	Tenns & Coaditious
	Enhanced Insect Resistance Management Compliance Assurance Program for Corn Borer Protected Bt Corn, Corn Rootworm-Protected Bt Corn, and Corn Borer / Corn Rootworm Protected Stacked Bt Corn.	483751-01	ABSTC	OWN	Terms & Conditions
	Baseline Assessment of BI Susceptibility of Com Earworm, <i>Helicoverpa zea</i> , to Cryl A.105; 2009 Collections and Assays (Lang, B. 2010)	48207401	Monsanto Company	OWN	IRM- Condition of Registration
	Baseline Susceptibility of the European Com Borer, Ostriula nubilasis, to Cry IA.105 and Cry2Ab2 Bt Proteins (Siegfried, B. and Spencer, T. 2010)	48207402	Moasante Company	DWN	IRM- Condition of Registration
	2010 Insect Resistance Management Compliance Assurance Program Report for Corn Borer Protected Bt Corn MON 89034 (EPA Reg. No. 524-575)		Молsanto Company	OWN	IRM- Condition of Registration
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date June 1, 2011	

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	DA	TA MATRIX			
Date: June 1, 2011		***************************************	EI	PA Reg. No./File Symbol: 524-575	Page 9 of 66
	N. Lindbergh Blvd., St. Louis, MO 63167			oduct: MON 89034	
Ingredient Bacillus thurings Identifier: MON-89Ø34-3)	iensis Cryl A. 105 and Cry2 Ab2 Proteins and the Genetic N	faterial (Vector PV	-ZMIR245) Necessary for th	eir Production in MON 89034 (OE	CD Unique
Guideline Reference Number	Guideline Stody Name	MRID Number	Submitter	Status	Note
	Baseline Susceptibility of Southwestern Corn Borer, Diatraea grandiosella, to Cry IA. 105 and Cry 2Ab2 B( Proteins (Song, Q., Sun, Y. and Wang, Q. 2009)	48207403	Monsanto Compan	y OWN	IRM- Condition of Registration
	Annual Sales report for MON 810 (EPA Reg.No. 524-489), MON 863 (EPA Reg. No. 524-528), MON 863 x. MON 810 (EPA Reg. No. 524-545), MON 88017 (EPA Reg. No. 524-551), MON 89034 (EPA Reg. No. 524-575) and MON 89034 x MON 88107 (EPA Reg. No. 524-576)	479614-01	Monsanto Compan	y OWN	Terms & Conditions
	Updated Compliance Assurance Plan, Educational Materials, IRM Monitoring, and a Remedial Action Plan for MON 89034 and MON 89034× MON 88017 Insect- Protected and Herbicide-Tolerant Corn (Keller, P. 2011)	479033501	Monsauto Compan	y OWN	Conditions of Registration
	Supplemental Information for MRID No. 46951402 "Amended Report for MSL-20072: Molecular analysis of Corn MON 89034".	471275-03	Monsanto Compan	y OWN	Product Characterization
	Supplemental Information for MRID No. 46951403 "Assessment of the Cryl A. 105 and Cry2Ab2 Protein Levels in Tissues of Insect-Protected Com MON 89034 Produced in 2005 U.S. Field Trials".	471275-05	Monsanto Compan	y OWN	Product Characterization
Signature	See Page 1 for Signature	. 1817 W. 172	Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Mana	Date June 1, 2011 ger	metabolis via

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401 M Street, S.W., Washingto	on, DC 20460. Do not send the form to this address.				
	עם	ATA MATRIX			
Date: June 1, 2011			EP.A	Reg. No./File Symbol: 524-575	Page 10 of 66
	N. Lindbergh Blvd., St. Louis, MO 63167			inet: MON 89034	
Ingredient Bacillus thuringi Identifier; MON-89Ø34-3)	ensis Cry I A. 105 and Cry2 Ab2 Proteins and the Genetic N	Material (Vector PV	-ZMIR245) Necessary for the	ir Production in MON 89034 (OE	CD Unique
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Bogdanova, N.N. 2006. Human Health and Environmental Assessment of the Plant-Incorporated Protectant Bacillus thuringiensis Cry1A. 105 and Cry2Ab2 Proteins Produced in Com MDN 89034.	469514-01	Monsanto Company	OWN	Product Characterization
885.1100	Rice, J.F., B.J. Wolff, J.R, Groat, N.K. Scaulon, J.C. Jennings, and J.D. Masucci. 2006. Amended Report for MSL-20072: Molecular Analysis of Corn MON 89034. Monsanto Technical Report MSL-20311.	469 <u>514</u> -02	Monsanto Company	DWN	Product Characterization
885.1100	Hartmann, A.J., K.E. Niemeyer, and A. Silvanovich. 2006. Assessment of the Cry1A.105 and Cry2Ab2 Protein Levels in Tissues of Insect-Protected Corn MON 89034 Produced in 2005 U.S. Field Trials. Monsanto Technical Report MSL-20285.	469514-03	Монѕаню Сотралу	OWN	Product Characterization
885.1100	Karunanandaa, K., J.J. Thorp, M.E. Goley, S.L. Levine, and A. Silvanovich. 2006. Characterization of the Cry2Ab2 Protein Purified from the Corn Grain of MDN 89034 and Comparison of the Physicochemical and Functional Properties of the Plant-Produced and E. coli-Produced Cry2Ab2 Proteins. Monsanto Technical Repon MSL-20071.	469514-04	Monsanto Company	OWN	Product Characterization
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manage	Date June 1, 2011	4

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	D/	ATA MATRIX			
Date: June 1, 2011		E	PA Reg. No./File Symbol: 524-575	Page 11 of 66	
Ingredient Bacillus thuring	N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 89034 7-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique			
Identifier: MON-89Ø34-3) Guideline Reference Number	Guideline Study Name	MRtD Number	Submitter	Status	Note
885.1100	Levine, S.L. and J. Uffman, 2006. Evaluation of the Functional Equivalence of the Cry2Ab2 Protein Produced in E. Coli and Bt Against a Sensitive Lepidopteran Species. Monsanto Teclinical Report MSL-20132.	469514-05	Monsanto Compan		Product Characterization
885.1100	Rice, J.F., B.J. Wolff, J.C. Jennings, and J.D. Masned. 2005. Summary of Southern Blot Analysis of MON 89034 and MON 89597 Corn. Monsanto Technical Report MSL-20068	466945-01	Monsanto Compan	y OWN	Product Characterization
885.1100	Goertz, B., T. Ganguly, J. Lee, T. Lee, and E.A. Ríce. 2005. Characterization of the Cry1A.105 Protein Purified from the Corn Grain of MON 89034 and Comparison of the Physicochemical and Functional Properties of the Plant-Produced and E.coli-Produced Cry1A.105 Proteins. Monsanto Technical Report MSL-19960.	466946-04	Monsanto Compan	ıy OWN	Product Characterization
	Supplemental Information for MRID No. 46951402 "Amended Report for MSL-20072: Molecular analysis of Corn MON 89034".	471275-03	Monsano Compan	ıy OWN	Product Characterization
	Supplemental Information for MRID No. 46951403 "Assessment of the Cry1A.105 and Cry2Ab2 Protein Levels in Tissues of Insect-Protected Corn MON 89034 Produced in 2005 U.S. Field Trials".	471275-05	Monsanto Compan	yOWN	Product Characterization
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Mana	Date June 1, 2011	

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	DA	TA MATRIX			
Date: June 1, 2011		EP /	A Reg. No./File Symbol: 524-575	Page 12 of 66	
	N. Lindbergh Blvd., St. Louis, MO 63167			duct: MON 89034	
ngredient Bacillus thurings dentifier: MON-89Ø34-3)	iensis Cry I A.105 and Cry2 Ab2 Proteins and the Genetic N	faterial (Vector PV	-ZMIR245) Necessary for the	ir Production in MON 89034 (OE	CD Unique
Suideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Bogdanova, N.N. 2005. Structural and Functional Similarity of the Cry1A.105 Protein to Cry1A Class of Bacillus thuringtensis Proteins. Monsanto Technical Report 05-RA-62-01.	466946-01	Monsanto Company	OWN	Product Characterization
860.1340	Dudin, Y.A and P. Chinnachirai. 2005. Qualitative Delection Method for the Cry2Ab2 Protein in Com Leaf and Seed of MON 89034 and MON 89597. Monsanto Technical Report 05-RA-39-04.	466945-03	Monsanto Company	OWN	Product Characterization
885.3050	Bounctte, K.L. 2006. An acute oral toxicity study in mice with Cry2Ab2 protein. Monsanto Study CRO-2005-049.	469514-06	Monsanto Company	OWN	Human Health Assessment
885,1100	Kapadia, S.A. and E.A. Rice. 2006. Assessment of the invitro Digestibility of the Cry2Ab2 Protein in Simulated Gastric Fluid. Monsanto Technical Report MSL-19931.	469514-07	Monsanto Company	OWN	Human Health Assessment
885.1100	Kupadia, S. and E.A. Rice. 2005. Assessment of the in vitra Digestibility of the Cry1A.105 Protein in Simulated Intestinal Fluid. Monsanto Technical Report MSL-19930.	469514-08	Monsanto Company	OWN	Human Health Assessment
Signature	Sec Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manage	Date June 1, 2011	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1

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	DA DA	ATA MATRIX	ST 2002ST 523		
Date: June 1, 2011		EP	A Reg. No./File Symbol: 524-575	Page 13 of 66	
	Address: N. Lindbergh Blvd., St. Louis, MO 63167 ienxis Cry1A.105 and Cry2Ab2 Proteins and the Genetic N	Material (Vector PV		oduct: MON 89034 cir Production in MON 89034 (OE	CD Unique
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885,1100	McCoy, R.L. and A. Silvanovich. 2005. Bioinformatics Analysis of the Cry1A, 105 Protein Utilizing the AD5, TOXIN5, and ALLPEPTIDES Databases. Monsanto Technical Report MSL-19686.	466946-05	Monsanto Company	OWN	Hunnan Health Assessment
885.1100	Thorp, J.J. and M.E. Goley. 2006. Assessment of the in vitro Digestibility of the Cry2Ab2 Protein in Simulated Intestinal Fluid. Monsanto Technical Report MSL-19938	469514-09	Monsanto Company	, OWN	Human Health Assessment
885.1100	McClain, J.S. and A. Silvanovich. 2006. Bioinformatics Evaluation of the Cry1A.105 Protein Utilizing the AD6, TOXINS, and ALLPEPTIDES Databases. Monsanto Technical Report MSL-20351.	469514-10	Monsunto Company	, OWN	Human Health Assessment
885,1100	Kapadia, S.A. and E.A. Rice. 2005. Assessment of the in vitro Digestibility of the Cry1A.105 Protein in Simulated Gastric Fluid. Monsanto Technical Report MSL-19929.	466946-06	Монѕаню Соптрану	OWN	Human Health Assessment
885.1100	Goley, M.E. and J.J. Thorp. 2005. Immunodetection of Cry2Ab2 and Cry1A.105 Proteins in Corn Grain from MON 89034 Following Heat Treatment. Monsanto Technical Report MSL-19899.	466946-07	Monsanto Company	y OWN	Human Health Assessment
885.3050	Bonnette, K.L. 2005. An Acute Oral Toxicity Study in Mice with Cry1A.105 Protein. Monsanto Study CRO-2005-050.	466946-03	Monsanto Company	y OWN	Human Health Assessment
Signature	See Page 1 for Signature	St.	Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manag	Date June 1, 2011 ger	25 ad 196 St

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	DA	ATA MATRIX			
Date: June 1, 2011			EP	A Reg. No./File Symbol: 524-575	Page 14 of 66
	Address: N. Lindbergh Blvd., St. Louis, MO 63167 iensis Cryl A.105 and Cry2 Ab2 Proteins and the Genetic N	Aaterial (Vector PV		oduct: MON 89034 eir Production in MON 89034 (OE	CD Unique
Identifier: MON-89Ø34-3)		,			<u> </u>
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	McClain, J.S. and A. Silvanovich. 2006. Bioinformatics Analysis of the Cry2Ab2 Protein Utilizing the AD6, TOXIN5, and ALLPEPTIDES Databases. Monsanto Technical Repon MSL-20307.	469514-11	Monsanto Company	OWN	Human Health Assessment
885.4050	Davis, S.W. 2006. Comparison of Broiler Performance and Careass Parameters When Fed Diets Containing MON 89034, Control or Commercial Com. Monsanto Spidy 05-01-50-13, Amended Report.	469514-12	Monsanto Company	, OWN	Human Health Assessment
N/A	MacRac, T.C., C.R. Brown, and S.L. Levine. 2006. Spectrum of Insecticidal Activity of <i>Bactillus thuringiensis</i> Cry1A.105 Protein. Monsanto Technical Report MSL- 20230.	469514-13	Monsanto Company	OWN	Environmental Assessment
N/A	MacRae, T.C., C.R. Brown, and S.L. Levine. 2006. Spectrum of Insecticidal Activity of <i>Bacillus rhuringiensis</i> Cry2Ab2 Protein. Monsanto Technical Report MSL- 20229.	469514-14	Monsanto Company	, OWN	Environmental Assessment
N/A	Headrick, J.M., O. Heredia, I.O. Oyediran, and T.T. Vauglin. 2006. Assessment of the Efficacy of Lepidopteran-protected Coril MON 89034 and MON 89597 Against Major Insect Pests in United States, Puerto Rico and Argentina During 2003-2004 Seasons. Monsanto Technical Report 05-RA-39-05.	469514-15	Monsanto Company	OWN	Environmental Assessment
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manag	Date June 1, 2011	

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	D/	TA MATRIX			
Oate: June 1, 2011				EPA Reg. No./File Symbol: 524-575	Page 15 of 66
	N. Lindbergh Blvd., St. Louis, MO 63167			Product: MON 89034	
Ingredient Bacillus rhuring Identifier: MON-89Ø34-3)	fensis Cry I A.105 and Cry2Ab2 Proteins and the Genetic N	Naterial (Vector PV	-ZMIR245) Necessary for	their Production in MON 89034 (OF	CD Unique
Guideline Reference Number	Guideline Study Name	MRtD Number	Submitter	Status	Note
885.4340	Teixeira, D. 2006. Evaluation of Dietary Effects of Lyophilized Leaf Tissue from Com MON 89034 in a Chronic Exposuze Study with Collembola (Folsomia candida). Monsanto Technical Report MSL-20169.	469514-16	Монѕалю Сотра	uiy OWN	Environmental Assessment
885.4340	Patmer, S.J. and H.O. Krueger. 2006. Evaluation of Exposure to MON 89034 with the Ctadoceran Daphnia magna: An acute static-renewal test with corn pollen. Monsanto Study WL-2005-011.	469514-17	Монѕаню Сотра	uiy OWN	Environmental Assessment
885.6200	Sindermann, A.B., I.R. Porell, and H.O. Krueger. 2006. Evaluation of Potential Effects of Exposure to Cry1A.105 Protein in an Acute Study with the Earthworm in an Artificial Soil Substrate. Monsaulo Technical Report MSL-20147.	469514- <b>t</b> 8	Monsanto Compa	iny OWN	Environmental Assessment
885.4380	Richards, K.B. 2006. Evaluation of the Dietary Effect(s) of a CrytA.105 Protein on Honeybee Larvae ( <i>Apls mellifera</i> L.). Monsanto Study CA-2005-07t.	469514-19	Monsanto Compa	nny OWN	Environmental Assessment
885.4380	Richards, K.B. 2006. Evaluation of the Dietary Effect(s) of a Cry1A.105 Protein on Adult Honeybees (Apis mellifera L.). Monsanto Study CA-2005-072	469514-20	Monsanto Compa	my OWN	Envizonmental Assessment
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Mar	Date June 1, 2011	

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Date: June 1, 2011 Page 16 of 66 EPA Reg. No./File Symbol: 524-575 Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167 Product: MON 89034 Bacillus thuringiensis Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Ingredient Identifier: MON-89Ø34-3) Guideline Reference Number Guideline Study Name MRID Number Submitter Status Note Paradise, M.S. 2006. Evaluation of Potential Dictary Effects of Cry1A.105 Protein on the Ladybird Beetle, Coleomegilla maculato (Colcoptera: Coccinellidae). Environmental 885,4340 Monsanto Technical Report MSL-20150. 469514-21 Mousanto Company OWN Assessment Paradise, M.S. 2006. Evaluation of Potential Dietary Effects of Cry2Ab2 Protein on the Ladybird Beetle, Culeopiegitla maculata (Colcoptera: Coccinellidae). Environmental Monsanto Technical Report MSL-20151. 469514-22 OWN 885,4340 Monsanto Company Assessment Teixeira, D. 2006. Evaluation of Potential Dietary Effects of Cry1A.105 Protein on Minute Pirate Bugs, Orins insidiosus (Hemiptera: Anthocoridae). Monsanto Environmental Technical Report MSL-20170. OWN Assessment 885.4340 469514-23 Monsanto Company Teixeira, D. 2006. Evaluation of Potential Dictary Effects of Crv2Ab2 Protein on Minute Pirate Bugs, Orius insidiosus (Hemiptera: Anthocoridae). Monsaulo Environmental 885.4340 Technical Report MSL-20171. 469514-24 OWN Assessment

469514-25

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Sindermann, A.B., J.R. Porch, and H.O. Krueger. 2006. Evaluation of Potential Effects of Exposure to Cry1A.105 Protein in an Acute Study with the Parasitic Wasp, Ichneumon prumissorius (Hymenoptera: Ichneumonidae).

Monsanto Technical Report MSL-20149.

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Name and Title

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	DA	ATA MATRIX			
Date: June 1, 2011			B	PA Reg. No./File Symbol: 524-575	Page 17 of 66
	N. Lindbergh Blvd., St. Louis, MO 63167		Pı	roduct: MON 89034	
Ingredient <i>Bacillus thuri</i> ng Identifier: MON-89Ø34-3)	giensis Cry1A.105 and Cry2Ab2 Proteins and the Genetic	Material (Vector PV	/-ZMIR245) Necessary for t	heir Production in MON 89034 (OF	ECD Unique
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885,4050	Gallagher, S.P. and J.B. Beavers, 2006. Evaluation of Potential Dietary Effects of MON 89034 with the Northern Bobwlite: an Eight-day Dietary Study with Corn Grain. Monsanto Technical Report WE-2005-012.	469514-27	Monsanto Compan	y OWN	Environmental Assessment
885.5200	Mneth, M., T. Curran, J. Warren, S. Dubelman, M. Glaspie, J. Murphy, S. Levine, J. Holtmeyer, and C. Jiang. 2006. Aerobic Soil Degradation of the Purified Cry2Ab2 and Cry1A.105 Proteins. Monsanto Technical Report MSL-20174.	469514-28	Monsanto Compan	y OWN	Environmental Assessment
N/A	Huesing, J.E., J.J. Duan, and S.L. Levine. 2006. Endangered Species Risk Assessment for Corn MON 89034. Monsanto Technical Report MSL0020394.	469514-29	Monsanto Compan	y OWN	Environmental Assessment
N/A	MacRac, T.C., C.R. Brown, S.L. Levine. 2005. Evaluation of the Potential for Interactions Between the Bacillus thuringieuxis Proteins Cry1A.105 and Cry2Ab2. Monsanto Technical Report MSL-19859.	466946-02	Monsanto Compan	y OWN	Environmental Assessment
885,4340	Sindermann, A.B., J.R. Porch, and H.O. Krueger. 2006. Evaluation of Potential Effects of Exposure to Cry2Ab2 Protein in an Acute Study with the Parasitic Wasp, <i>Ichneumon promissorius</i> (Hymenoptera; Ichneumonidae). Monsanto Technical Report MSL-20148.	469514-26	Monsanto Compan	y OWN	Environmental Assessment
Signature	See Page 1 for Signature		Name and Title J. Austin Burus, Ph.D. Regulatory Affairs Mana	Date June 1, 2011	

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Date: June 1, 2011			EP	A Reg. No./File Symbol: 524-575	Page 18 of 6
Applicant's/Registrant's Name &					
	N. Lindbergh Blvd., St. Louis, MO 63167			odnet: MON 89034	
ngredient Bacillus thuring deutifier: MON-89Ø34-3)	giensis Cry1A,105 and Cry2Ab2 Proteins and the Genetic I	Material (Vector PV	/-ZMIR245) Necessary for th	eir Production in MON 89034 (O	ECD Unique
Svideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Palmer, S.J. and H.O. Krueger. 2000. Insect Protection Protein 2: An Acute Toxicity Study With the Earthworm in an Artificial Soil Substrate. Monsanto Technical Report MSL-16177	450863-13	Monsanto Company	OWN	Environmental Assessment
885.4380	Maggi, V.L. 2000. Evaluation of dietary effect(s) of purified <i>Bacillus thuringiensis</i> Cry2Ab2 protein on honey bee larvae. Monsanto Technical Report MSL-16961.	453371-02	Monsanto Company	OWN	Environmental Assessment
885,4340	Teixeira, D. 2000. Assessment of Chronic Toxicity of Cotton Tissue Containing Insect Protection Protein 2 to Collembola (Folsomia candida), Antended report.  Monsanto Technical Report MSL-16174.	450863-14	Monsanto Company	own	Environmenta Assessment
885.4340	Palmer, S. and H. Krueger. 2000. Insect Protection Protein 2: A Dietary Toxicity Study with Parasitic Hymenoptera (Nasonia vitripennis). Monsanto Technical Report MSL-16173.	450863-10	Monsanto Company	OWN	Environmental Assessment
885.4380	Maggi, V.L. 2000. Evaluation of the Dictary Effect(s) of Insect Protection Protein 2 on Adult Honey Bees (Apis mellifera L.). Monsanto Technical Report MSL-16176.	450863-08	Монзапю Сотрану	OWN	Environmenta Assessment
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manage	Date June 1, 2011	

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	D.	TA MATRIX				
Date: June 1, 2011				EPA Reg. No	o./file Symbol: 524-575	Page 19 of 66
	N. Lindbergh Blvd., St. Louis, MO 63167			Product: N	MON 89034	
tngredient Bacillus thuring Identifier: MON-89Ø34-3)	riensis Cry IA.105 and Cry2Ab2 Proteins and the Genetic	Material (Vector PV	/-ZMIR245) Necessary f	or their Produ	uction in MON 89034 (OE	CD Unique
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter		Status	Note
N/A	Head, G. 2006. Insect Resistance Management Plan for Second Generation Lepidopteran-Protected Corn, MON 89034. Monsanto Technical Report 06-RA-39-06.	. 469514-30	Monsa <sub>l</sub> no Com	pany	OWN	IRM
	Bogdanova, N. and A. Crawford (2007), Public Interest Document Supporting Registration of Bacillus thuringicusis Cry1A.105, Cry2Ab2 and Cry3Bb1 Proteins in Insect-Protected Com MON 89034 and MON 89034 x MON 88017	472797-01	Monsanto Com	pany	OWN	Benefits
	Bogdanova, N., S. Dubelman, M. Mueth, J. Murphy and A. Silvanovich (2007). Responses to EPA Questions Regarding Application 524-LTL to register Insect- Protected Corn MON 89034 (MRID 46951428)	471403-01	Monsanto Com	ipany	OWN	Misc.
	Bogdanova, N., (2007) Responses to EPA Questions Regarding Applications 524-LTL and 524-LTL to Register fuscet-Protected Corn MON 89034 and MON 89034 x MON 88017 (MRtD 46951400 and 46951300)	471275-01	Monsanto Com	ipaity	OWN	Misc.
	Bogdanova, N, (2007). Supplemental Information to Address EPA Questions Regarding Applications 524-LTL and 524-LTL to Register Insect-Protected Com MON 89034 and MON 89034 x MON 88017 (MRID 46951400 and 46951300)	470794-02	Monsanto Con	ipany	OWN	Misc.
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D Regulatory Affairs M		Date June 1, 2011	

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	DA	ATA MATRIX			
Date: June 1, 2011				A Rcg. No./File Symbol: 68467-2	Page 20 of 66
Applicant's/Registrant's Name & Monsanto Company, 800 I	Address: N. Lindbergh Blvd., St. Louis, MO 63167		Pro	duct: Herculex® I Insect Prod	tection
ngredient B.t. Cry1F prote	in and the genetic material necessary for production (plass	mid insert PHP8999	)) in maize (OECD Identifier:	DAS-Ø15Ø7-1)	
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Acute oral toxicity in mice: Cry IF Bacillus Vuuringienris subsp. aizawai delta endotoxin	44691101	68467	PER	
	Effectiveness data for Bacillus thuringiensis var. aizawai Cry1F insect control protein as expressed in maize	44691102	68467	PER	
	Background document on resistance management	44691103	68467	PER	
	Product Characterization Data for Bacithis thuringiensis var. aizawai Cry IF Insect Control Protein as expressed in Maize	447 [480]	68467	PER	
	Characterization of Gene Inserts-Bacillus thuringiensis var. aizawai Cry1F Insect Control Proteins Expressed in Maize	447   4802	68467	PER	
	Equivalency of Microbial and Maize Expressed Cry1F Protein; Characterization of Test Substances for Biochemical and Toxicological Studies. In Vitro Digestibility of Microbial and Maize Expressed Cry1F Protein Under Simulated Gastric Conditions	44714803	68467	PER	
Signature  See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manag	Date June 1, 2011		

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	D	ATA MATRIX			
Date: June 1, 2011		ageneral ac	EP/	A Reg. No./File Symbol: 68467-2	Page 21 of 66
Applicam's/Registram's Name & Monsanto Company, 800 I	Address: N. Lindbergh Blvd., St. Louis, MO 63167		Pro	duct: Herculex® I Insect Pro	tection
Ingredient B.t. Cry IF prote	ein and the genetic material necessary for production (plas	mid insert PHP8999	9) in maize (OECD Identifier:	DAS-Ø15Ø7-1)	
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Quantitative ELISA Analysis of Cry1F Expression levels in Maize MPS Inbred Lines 1360, 1365, 1366, and 1369. (Interim Report)	44714804	68467	PER	
	Comparison of Amino Acid Sequence Similarity of . Cryl F and PAT Proteins to Known Allergen Protein	44971701	68467	PER	
	Microbial B.t. Cry IF (truncated) Delta-Endotoxin: Maize-Inscet-Pest Susceptibility Study	45020101	68467	PER	
	Characterization of inserted genes in Cry1F maize line 1507	45020102	68467	PER	
	Effectiveness Data for Bacillus Unuringiensis var. aizawai Cry1F Insect Control Protein as Expressed in Maize	44691102	68467	PER	
	Characterization of Expressed Cry1F Protein in Maize Tissues (Pollen, Grain, Grain-Containing Feed, and Purified Maize-Expressed Cry1F Protein) and Microbial Expressed Cry1F Della Endotoxin by Biological and Biochemical Procedures	45020103	68467	PER	
	Quaptitative ELtSA Analysis of Cry1F and PAT Expression levels in and Compositional Analysis of Maize Inbred and Hybrid Lines 1362 and 1507	45020104	68467	PER	
Signature	See Page I for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manag	Date June 1, 2011	

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	D/	ATA MATRIX			
Date: June 1, 2011			76 (2007 o 1975) - 144, 25 (2007 o 1975)	EPA Reg. No./File Symbol: 68467-2	Page 22 of 66
Applicant's/Registrant's Name &					1
	N. Lindbergh Blvd., St. Louis, MO 63167	····	<u> </u>	Product: Herculex® I Insect Pro	tection
Ingredient B.I. Cry1F prote	ein and the genetic material necessary for production plasn	nid insert PHP8999	) in maize (OECD Identifi	ier: DAS-Ø15Ø7-1)	
Guitleline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
gg-Mile.	Environmental Fate of Cry1F Protein incorporated into Soil	45020105	68467	PER	
	Cryl F Baciflus thuringiensis var. aizawai Delta Endotoxin: An Acute Toxicity Study with the Earthworm in an Articial Soil Substrate	45020106	68467	PER	
	Chronic exposure of Folsomia candida to bacterially expressed Cry1F protein	45020107	68467	PER	
OECD 202	B.t. CrylF delta endotoxin: A 48-hour static-renewal acute toxicity test with the Cladoceran (Daphnia magna) using bacterially expressed B.t. CrylF delta endotoxin, and pollen from maize expressing B.t. CrylF delta endotoxin	45020108	68467	PER	
885.4340	Cry1F Bacifins thuringlensis var. aizawai delta endotoxin: A dietary study with green lacewing larvac	45020109	68467	PER	
885.4340	Cryl F Bacillus thuringiettsis var. aizawai delta endotoxin: A dictary study with the ladybird beetle	45020110	68467	PER	
Signature	See Page 1 for Signature	**************************************	Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Ma	• • • • • • • • • • • • • • • • • • •	9404

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Date: June 1, 2011	Special Color St. Tables St. Associate St. Associate St.			EPA Reg. No./File Symbol: 68467-2	Page 23 of 66
Applicant's/Registrant's Name & Monsanto Company, 800 l	Address: N. Lindbergh Bivd., St. Louis, MO 63167			Product: Herculex® I Insect Pro	lection
Ingredient B.t. Cry1F prote	ein and the genetic material necessary for production (plas	mid insert PHP8999	9) in maize (OECD Ident	ifier: DAS-Ø15Ø7-1)	
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Cry1F Bacillus thuringiensis var. aizawai delta endotoxin: A dietary toxicity study with parasitic hymenoptera	45020111	68467	PER	
71-2	Transgenic com expressing <i>Bacillus thuringiensis</i> var. aizawai ( <i>B.t.</i> ) Cry IF della endotoxin: A dictary toxicity study with Northern bobwlite	45020112	68467	PER	
	Field survey of beneficial arthropods associated with Bacillut thuringiensis Cry1F maize	45020113	68467	PER	
	Efficacy of CryIF events TC1360 and TC1507	45020114	68467	PER	
	Cry1F binding studies	45020115	68467	PER	
	Resistance management plan for transgenic maize expressing the Cry IF insecticidal protein from Bacillus fluringiensts var. aizawai	45020116	68467	PER	
Signature See Page 1 for Signature			Name and Title J. Austin Burns, Plt.D Regulatory Affairs M	anager	ternal Use Copy

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	D/	ATA MATRIX			
Daic: June 1, 201 t			E	PA Reg. No/File Symbol: 68467-2	Page 24 of 66
Applicant's/Registrant's Name & Monsanto Company, 800 l	Address: N. Lindberglı Blvd., St. Louis, MO 63167			roduct: Herculex® I Insect Prote	ection
Ingredient B.t. Cry IF prote	ein and the genetic material necessary for production (plas	mid insert PHP8999	9) in maize (OECD Identifie	r: DAS-Ø15Ø7-1)	
Guideline Reference Number	Guideline Statty Name	MRID Number	Submitter	Status	Note
	Supplement to MRID 44714801: Supplemental data - Product characterization data for Bacillus fluuringiensis var. aizawai: Cry1F control protein as expressed in maize	45020117	68467	PER	***
	Supplement to MRID 44691101: Supplemental data - Acute oral toxicity in mice: Bacillus thuringiensis var. aizawai Cry1F delta endotoxin	45020118	68467	PER	
	Phosphinothricin acctyltrausferase (PAT) protein: In vitro digestibility study	45041501	68467	PER	
	Non-target exposure and risk assessment for environmental dispersal of Cry1F maize pollen	45041502	68467	PER	
	Evaluation of the dietary effect(s) on honeybee development using bacterially expressed B.r. Cry1F delta endotoxin and pollen from maize expressing B.r. Cry1F delta endotoxin	45041503	68467	PER	
	Waiver request: Fish toxicity test with transgenic maize (com) containing Bacillus thuringiensis var. aiaqoi (B.r.) Cry1F delta endotoxin	45044201	68467	PBR	
Signature See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Mana	Date June 1, 2011		

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	D <sub>i</sub>	ATA MATRIX			
Date: June 1, 2011			E	PA Reg. No./File Symbot: 68467-2	Page 25 of 66
Applicant's/Registrant's Name & Address:  Monsanfo Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167			Р	roduct: Herculex® 1 Insect Prod	tection
tugredient B.t. Cry1F prote	ein and the genetic material necessary for production (plas	mid insert PHP8999	) in maize (OECD Identifie	r: DAS-Ø(5Ø7-1)	
Guideline Reference Number	Guidetine Study Name	MRtD Number	Submitter	Starus	Note
	High dose demonstration of Cry (F events TC1360 and TC1507: European corn borer	45 <u>1</u> 3110t	68467	PER	
	Toxicity of the CryIF protein to neonate tarvae of the inonarch buttefly (Danaus plexippus (Linneaus))	45131102	68467	PER	
	Public interest document for Cry1F-protected corn	45131103	68467	PER	
	Thermolability of Cry1F (truncated) delta endotoxin	45274801	68467	PER	
,	Compositional analysis of maize MPS hybrid line 1507	45274802	68467	PER	
	Cry1F taterat flow test kit procedure for analyzing Cry1F com grain	45279301	68467	PER	
	Method validation report for the determination of Cry1F delta endotoxin protein in grain by Enzyme-Linked Immunosorbent Assay	45279302	68467	PER	
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Mana	Date June 1, 2011	

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	DA	TA MATRIX			
Datc: June 1, 2011			E	PA Reg. No./File Symbol: 68467-2	Page 26 of 66
	N. Lindbergh Blvd., St. Louis, MO 63167			oduct: Herculex® 1 Insect Pro	tection
	ein and the genetic material necessary for production (plas				
Guideline Reference Number	Guideline Study Name  Supplement to MRID 45131102: Supplemental data - High dose demonstration of Cry1F events TC1360 and TC1507: European comborer	45307701	Submitter 68467	Status PER	Note
	Waiver request: Fish toxicity test to assess the potential effects of maize containing Bacillus thuringiensis var. aizawai (BI) Cry II <sup>st</sup> insecticidal protein (ICP) in native fish	45307702	68467	PER	
	Supplement to MRID 45020109; Cry1F Bucillus thuringiensis var. aizawai delta endotoxin; A dictary toxicity study with green lacewing larvac	45307801	68467	PER	- Canada Sana
	Supplement to MRID 45020110; Cry [F Bacillus t/mringiensis var. aizawai delta endotoxin: A dietary toxicity study with green ladybird beetle	45307802	68467	PER	
	Supplement to MRID 45020111: Cry1F Bacillus fluvingiensis var. aizawai delta endotoxin: A dietary toxicity study with parasitic hymenoptera	45307803	68467	PER	
	Supplement to MRfD 45020106: Cry1F Bacillus thuringiens is var. aizawai delta endotoxin: An acute toxicity study with the earthworm in an artificial soil substrate	45307804	68467	PER	
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Mana	Date June 1, 2011 ger	

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	DA	TA MATRIX			
Date: June 1, 2011		N-1000		EPA Reg. No./File Symbol: 68467-2	Page 27 of 66
Applicant's/Registrant's Name & Monsanto Company, 800	Address: N. Lindbergh Blvd., St. Louis, MO 63167			Product: Herculex® I Insect Pro	otection
Ingredient B.t. Cry IF prote	ein and the genetic material necessary for production (plas	mid insert PHP8999	9) in maize (OECD Identif	fier: DAS-Ø15Ø7-I)	
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Supplement to MRID 45041503: Evaluation of the dietary effect(s) on honeybee development using bacterialty expressed B.t. Cry1F delta endotoxin and pollen from maize expressing B.t. Cry1F delta endotoxin	45307805	68467	PER	
	Exposure and risk assessment of Hereulex t Bi field corn pollen to Kamer blue butterfly	455 <u></u> t2901	68467	PER	NO. 10 10 10 10 10 10 10 10 10 10 10 10 10
	Nutritional equivatency of B.t. Cry1F maize - pouttry feeding study	4562200t	68467	PER	
	Field survey of beneficial arthropods associated with Bacillus thuringiensis Cry tF maize	45648001	68467	PER	
	Field surveys of non-target invertebrate populations in B.t. com	456 <u>52001</u>	80778	PER	
	Development and characterization of Enzyme-Linked Immunosorbent Assay (ELISA) for detection of Cryt F protein	4568560 t	68467	PER	
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Ma	Date June 1, 2011	

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	D/	ATA MATRIX			
Date: June 1, 201t			E	EPA Reg. No./File Symbol; 68467-2	Page 28 of 66
	N. Lindbergh Blvd., St. Louis, MO 63167			Product: Herculex® I Insect Profe	ection
Ingredient B.t. Cry1F prote	ein and the genetic material necessary for production (plass	mid insert PFIP8999	) in maize (OECD Identifie	er: DAS-Ø[5Ø7-1)	
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Independent laboratory validation of method GRM 02.13, determination of Cry1F delta endotoxin protein in comgrain by an of Enzyme-Linked Immunosorbent Assay	45685602	68467	PER	
	Supplement to MRID 45131102: Toxicity of the Cry1F protein to neonate larvae of the monarch binterfly (Danaus plexippus (Linneaus))	45759701	68467	PER	
	Stewardship of Hercalex I Insect Protection with respect to the secondary lepidopteran pest, western bean eutworm (Richia albicosta Smith)	45896501	68467	PER	
	Lack of cross reactivity between Cry1F protein in Herculex I maize and the dust mite Der p7 protein with human sera positive for Der p7-lgE	46444001	68467	PER	
	Monitoring the susceptibility of European com borer to Cry1Ab and Cry1F Bt proteins: Results from the 2004 collections and diapansing larvae collected in 2003	46583101	80778	PER	
	Stewardship of event TC1507 maize with respect to the secondary lepidopleran pests lesser corn stalk borer (Elasmopalpus lignoseffus Zeller), southern corn stalk borer (Diatraea crambidiodes Grote), and sugarcane borer (Biatraea saccharafis Fabricius)	46600201	68467	PER	
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Man	Date June 1, 2011 ager	

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	D/	ATA MATRIX			
Date: June 1, 2011				EPA Rcg. No./File Symbol: 68467-2	Page 29 of 66
Applicant's/Registrant's Name &	Address:	***			
Monsanto Company, 800 1	N. Lindbergh Blvd., St. Louis, MO 63167	20120		Product: Herculex® I Insect Prote	ection
Ingredient B.t. Cry1F prote	ein and the genetic material necessary for production (plas	mid insert PHP8999	9) in maize (OECD Identifi	er: DAS-Ø15Ø7-1)	
Ouideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Slide presentation summarizing European com borer and Cry1F resistance monitoring update	46695801	68467	PER	
age.	lusect resistance management compliance assurance program report for corn borer-protected Bt com	46747801	80778	PER	22
	Field surveys of non-target invertebrate populations in Bt corn: Supplement to MRID No. 45652001	46784601	80778	PER	
	Monitoring the susceptibility of corn lepidopteran pests to Cry1Ab and Cry1F proteins: 2005 monitoring results	46874901	80778	PER	
	Research results on 2004 European corn borer collections from Hamilton County, lowa: Ctyl F	47011201	68467	PER	
	Insect resistance management compliance assurance program report for com borer-protected Bt com, com rootworm-protected Bt com, and com borer/com rootworm protected stacked Bt com	47044401	80778	PER	
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Man	Date June 1, 2011	en sedest (CAS)

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Agency, 401 M Street, S.W., v	Vashington, DC 20460. Do not send the form to this address				
	DA	TA MATRIX	<del></del>		<del></del>
Date: June 1, 2011			EP.	A Reg. No./File Symbol: 68467-2	Page 30 of 66
	N. Lindbergh Blvd., St. Louis, MO 63167			oduct: Herculex® I Insect Pro	tection
Ingredient B.t. Cryl F prote	in and the genetic material necessary for production (plass	nid insert PHP8999	) in maize (OECD tdeutifier:	DAS-Ø15Ø7-1)	
Guirleline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Monitoring the susceptibility of corn lepidopteran pests to Cry1Ab and Cry1F proteins: 2006 monitoring results	47118401	80778	PER	
	Soil accumulation of Cry1F after three years of cropping with Herculex 1 com	47120701	68467	PER	
	TC 1507 maize and fall armyworm in Puerto Rico	47176001	68467	PER	- <u> </u>
	Proposed revisions to IRM-related registration requirements for Cry1 plant-incorporated protectants in field com	47407001	80778	PER	
	Monitoring the susceptibility of corn lepidopteran pests to Cryl Ab and CrylF proteins: 2007 monitoring results	47413901	80778	PER	
	Proposed revisions to IRM-related registration requirements for Cry1 plant-incorporated protectants in field corn	47543901	80778	PER	
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manag	Date June 1, 2011	

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Date: June 1, 2011		400000	54553c	EPA Rcg. No./File Symbol: 68467-2	Page 31 of 66
Applicant's/Registrant's Name & Monsanto Company, 800 N	Address: V. Lindbergh Blvd., St. Louis, MO 63167			Product: Herculex®   Insect Pr	otection
Ingredient B.t. CrylF prote	in and the genetic material necessary for production (plass	mid insert PHP8999	e) in maize (OECD Identi	ifier: DAS-Ø15Ø7-1)	
Guideline Reference Number	Guideline Study Name	MRID Number	Subnutter	Status	Note
	Monitoring the susceptibility of corn lepidopteran pests to Cryl Ab and Cryl F proteins: 2008 monitoring results	47841801	80778	PER	
	Monitoring the susceptibility of com lepidopteran pests to Cry1Ab and Cry1F proteins; 2009 monitoring results	47971001	80778	PER	
	Production Report and Certificate of Analysis of Truncated Cry1F (TSN104550)	48193001	68467	PER	
	2010 Insect Resistance Management Compliance Assurance Program for Corn Borer Protected Bt Com, Corn Rootworm Protected Bt Com, and Corn Borer/Com Rootworm-Protected Stacked Bt Com	48375001	80778	PER	
	Enhanced fiscet Resistance Management Compliance Asstrance Program for Corn Borer Protected Bt Corn, Corn Rootworm Protected Bt Corn, and Corn Borer/Corn Rootworm-Protected Stacked Bt Corn	48375101	80778	PER	
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Pl. D Regulatory Affairs M	24 41 PER 20 PER	

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Date: June 1, 2011	2000/2004 47550/2004 2007 2007	EPA R	EPA Reg. No./File Symbol: 524-551		
	N. Lindbergh Blvd., St. Louis, MO 63167			e: MON 88017	
Ingredient B.t. Cry3Bb1 pro	tein and the genetic material (vector ZMIR39) necessary f		event MON 88017 corn (OECD	Unique Identifier: MON-88Ø1	
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Conditions of Registration for MON 88017 (EPA Reg. No.524-551) and MON 89034 x MON 88017 (EPA Reg. No.524-576), and Response to EPA's Request for Additional Information on Monsanto's Resistance Com Rootscorp (CRW) Monitoring Program.	484368-01	Monsanto Company	OWN	Terms & Conditions
	Conditions of Registration for MON 88017 (EPA Reg. No. 524-551) and Conditions of Registration for MON 89034 x MON 88017 (EPA Reg. No. 524-576).	484368-01	Monsanto Company	OWN	Terms & Conditions
	Enhanced Insect Resistance Management Compliance Assurance Program for Corn Borer Protected Bt Com, Com Rootworn-Protected Bt Corn, and Corn Borer / Corn Rootworm Protected Stacked Bt Corn.	483751-01	ABSTC	PER	Ternis & Conditions
	Annual Sales Report for MON 810, MON 863, MON 863 × MON 810, MON 88017, MON 88017 × MON 810, MON 89034, MON 88017 × MON 89034, and MON 88017 × MON 89034 × TC1507 × DAS-59122-7 (EPA Reg. Nos. 524-489, 524-528, 524-545, 524-551, 524-552, 524-575, 524-576, and 524-581).	483678-01	Monsanto Сонграну	OWN	Terms & Conditions
	2009 Season Monitoring for the susceptibility of Neonate Western Corn Rootwonn Larvae to the Bacillus thuringiensis Cry3Bb1 Protein.	N/A	Monsanto Company	OWN	Terms & Conditions
	2009 Season Monitoring for the Susceptibility of Neonate Weslern Corn Rootworm Larvae to the Bacillus thuringiensis Cry3Bb! Protein.	4820 <u>80-</u> 01	Monsanto Company	OWN	Terms & Conditions
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manag	Date June 1, 2011 er	1977/1970/00/00

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	DA	ATA MATRIX			
Date: June 1, 2011			EPA Reg. No./File Symbol: 524-551 Pa		
Monsanto Company, 800	Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167			Product: MON 88017	
Ingredient B./. Cry3Bb1 pro	tein and the genetic material (vector ZMIR39) necessary t	or its production in	event MON 88017 com (6	OECD Unique Identifier: MON-889	Ø17-3)
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	2009 Insect Resistance Management Compliance Assurance Program Report for Corn Borer-Protected Bt Com (EPA Reg. Nos. 524-489, 68467-2, 67979-1, and 29964-3), Com Rootworm-Protected Bt Com (EPA Reg. Nos. 524-528, 524-551, 68467-5, 67979-5, and 29964-4), and Com Borer/Com Rootworm-Protected Stacked Bt Com (EPA Reg. Nos. 524-545, 524-552, 524-576, 68467-6, 67979-8, and 29964-5).	479710-01	ABSTC	PER	Terms & Conditions
	Animal Sales report for MON 810 (EPA Reg.No. 524-489), MON 863 (EPA Reg. No. 524-528), MON 863 x MON 810 (EPA Reg. No. 524-545), MON 88017 (EPA Reg. No. 524-551), MON 89034 (EPA Reg. No. 524-575) and MON 89034 x MON 88107 (EPA Reg. No. 524-576).	479614-01	Monsanto Comp.	any OWN	Terms & Conditions
	2008 Season Monitoring for the Susceptibility of Neonate Western Corn Rootworm Larvae to the Bacillus thoringiensis Cry3Bb1 Protein.	4788 <u>46</u> -01	Monsanio Comp	any OWN	Terms & Conditions
	2008 threet Resistance Management Compliance Asstrance Program Report for Com Borer-Protected Bt Com (EPA Reg. Nos. 524-489, 68467-2, 67979-1, and 29964-3), Com Rootworm-Protected Bt Com (EPA Reg. Nos. 524-528, 524-551, 68467-5, 67979-5, and 29964-4), and Com Borer/Corn rootworm-Protected Stacked Bt Com (EPA Reg. Nos. 524-545, 524-552, 68467-6, 67979-8, and 29964-5).	476633-01	ABSTC	PER	Terins & Conditions
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs M	Date June 1, 2011  Anager	

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	D/	ATA MATRIX			
Date: June 1, 2011			EPA Reg	No./File Symbol: 524-551	Page 34 of 66
Applicant's/Registrant's Name & Monsanto Company, 8 <b>00</b> 1	Address: N. Lindberglu Blvd., St. Louis, MO 63167		Product:	MON 88017	
Ingredient B.t. Cry3Bb1 pro	tein und the genetic material (vector ZMIR39) necessary	for ils production in	event MON 88017 corn (OECD U	nique fdentifier: MON-88Ø1	7-3)
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Annual Sales Report for YieldGard Corn Borer Curn (EPA Reg. No. 524-489), YieldGard Rootworm Corn (EPA Reg. No. 524-528), YieldGard Phis Corn (EPA Reg. No. 524-545), MON 88017 (EPA Reg. No. 524- 551), and MON 88017 × MON 810 (EPA Reg. No. 524- 552).	476631-01	Munsanto Company	OWN	Terms & Conditions
	2006 Insect Resistance Management Compliance Assurance Program for Corn Borer-Protected Bt Com, Corn Ruotworm-Protected Bt Corn and Com Borer/Corn Rootworm-Protected Stacked Bt Corn. (ABSTC Report).	470444-01	ABSTC	PER	Ternis & Conditions
	Submission of Annual Sales Report for YieldGard* Corn Borer com (EPA Reg. No. 524-489), YieldGard* Rootworm com (EPA Reg. No. 524-528), YieldGard* Phis corn (EPA Reg. No. 524-545), MON 88017 (EPA Reg. No. 524-551) and MON 88017 x MON 810 (EPA Reg. No. 524-552), (2007).	470431-01	Monsanto Company	OWN	Terms & Conditions
	Susceptibility of Neonate Rootworm Larvae to the Cry3Bb1 toxin from Bacillus thuringiensis: 2005 Data Summary.	469491-01	Monsanto Company	OWN	Terms & Conditions
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date June 1, 2011	

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	D/	ATA MATRIX				
Date: June 1, 2011				EPA Reg. No	/File Symbol: 524-551	Page 35 of 66
Applicant's/Registrant's Name & Monsanto Company, 800 l	Address: N. Lindbergh Blvd., St. Louis, MO 63167			Product: M	ON 88017	
Ingredient B.t. Cry3Bb1 pro	tein and the genetic material (vector ZMIR39) necessary	for its production in	event MON 88017 corn	(OECD Uniqu	te Identifier: MON-88Ø	17-3)
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter		Status	Note
885.1100	Sidhu, R. S. (2004). Human Health and Environmental Assessment of the Plant-Incorporated Protectant <i>Bacillus</i> thuringiensis Cry3Bb1 Protein Produced in MON 88017. MSL-18835	461817-01	Monsanto Com	pany	OWN	Product Characterization
885,1100	Beasley, K. A., H.M. Anderson., P.B. Wimberley, D.W. Mittank., and R.P. Lirette. (2002). Molecular analysis of YieldGard*Rootworm/Roundup Ready*Corn Event MON 88017. MSL-17609	461817-02	Monsanto Cont	pany_	OWN	Product Characterization
885.1100	Bhakta, N. S., A. J. Hartmann, and J. C. Jennings (2003). Cry3Bb1 and CP4 EPSPS Protein Levels in Corn Tissues Collected from MON 88017 Corn Produced in U.S. Field Trials Conducted in 2002. MSL-18823	461817-03	Monsanto Com	pany	OWN	Product Characterization
885.1100	Duan, J. J., M. S. Paradise and C. Jiang (2003). Evaluation of Functional Equivalence of Two Cry3Bb1 Protein Variants Against Susceptible Colcopteran species. MSL-18799	461817-04	Monsanto Com	pany	OWN	Product Characterization
885.1100	Hileman, R. E. and J. D. Astwood (2001). Additional Characterization of the Cry3Bb1 Protein Produced in MON 863. MSL-17137	454240-10	Monsanto Com	pany	OWN	Product Characterization
Signature	See Page I for Signature		Name and Title J. Austin Burns, Ph.D Regulatory Affairs		Date June 1, 2011	

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	D/	ATA MATRIX			
Oate: June 1, 2011			EPA Reg	. No./File Symbol: 524-551	Page 36 of 66
	Applicant's/Registrant's Name & Address:  Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167				
Ingredient B.t. Cry3Bb1 pro	tein and the genetic material (vector ZMfR39) necessary	for its production in	event MON 88017 corn (OECD L	nique Identifier: MON-88Ø	17-3)
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Hileman, R. E., G. Holleschak, L. A. Turner, R. S. Thoma, C. R. Brown and J. D. Astwood (2001). Characterization and Equivalence of the Cry3Bb1 Protein Produced by E. coli Fermentation and MON 863. MSL-17274	455382-01	Monsanto Company	OWN	Product Characterization
860.1340	Brown, M. (2003). TraitChek <sup>TM</sup> Cry3Bb Lateral Flow Test Strip and SeedChek <sup>TM</sup> Cry3Bb ELISA Performance Verification for Corn Seed, Leaf, and Composite Testing. MSL-19581, in unpublished study conducted by Strategies Diagnostics, Inc.	463942-01	Monsanto Company	OWN	Product Characterization
885.110 <u>0</u>	Dudin, Y. A., B-P. Tonnu, L. D. Albee and R. P. Lirette (2001). Amended Report for MSL-16559: B.r. Cry3Bb1.11098 and NPTII Protein Levels in Sample Tissue Collected from MON 863 Grown in 1999 Field Trials. MSL-17t81	454240-01	Monsanto Company	OWN	Product Characterization
885.1100	Supplemental Information for "Evaluation of Functional Equivalence of Two Cry3Bb1 Protein Variants Against Susceptible Colcopteran Species" (MRID No. 461817-04)	465783-03	Monsanto Company	own	Product Characterization
885.1109	Thuma, R. S., G. Holleschak, R. E. Hileman and J. D. Astwood (2001). Primary Structural Protein Characterization of MON 863 Cry3Bb1.11098 Protein Using N-terminal Sequencing and MALDt Time of Flight Mass Spectrometric Techniques. MSL-17154	454240-11	Monsanto Company	OWN	Product Characterization
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date June 1, 2011	

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	DA DA	TA MATRIX			
Date: June 1, 2011			E	PA Reg. No./File Symbol: 524-551	Page 37 of 66
Applicant's/Registrant's Name &					
	N. Lindbergh Blvd., St. Louis, MO 63167 tein and the genetic material (vector ZMIR39) necessary f	or its production in		roduct: MON 88017	17 2)
Gnideline Reference Number	Gnideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Submission of Supplemental Data (May 21, 2001) in Support of the Application for Registration of MON 863; Com Rootworm Protected Com (Vector ZMIRI3L); EPA File Symbol 524-LEI.	N/A	Monsanto Compan		Product Characterization
885.1100	Dudin, Y., B-P. Tomu and R. P. Lirette (2001). Cry3Bb1, Cry1Ab and NPTH Protein Levels in the Dual- trait Maize Hybrid MON 863 x MON 810 Produced in Argentinian Field Trials Conducted During the 1999-2000 Growing Season. MSL-17266	457917-02	Monsanto Compan	ıy OWN	Product Characterization
885.1100	Holleschak, G., T. C. Lee, R. E. Hileman, P. D. Pyla, and J. D. Astwood (2001). Amended Report for MSL-15835: Assessment of the Equivalence of B.t. Protein 11098, B.r. Protein 11231 and NPT1t Protein Expressed in Com Events MON 853 and MON 860 to Microbial Sources. MSL-17222	454240-04	Monsanto Compan	sy OWN	Product Characterization
885.tt00	Supplemental Information for "Cry3Bb1 and CP4 EPSPS Protein Levels in Corn Tissues Collected from MON 88017 Corn Produced in U.S. Field Trials Conducted in 2002" (MRID No. 461817-03)	465783-02	Monsanto Compan	ıy OWN	Product Characterization
885,1100	Holleschak, G., R. E. Hileman, and J. D. Astwood (2001). Amended Report for MSL-16596: Assessment of the Physicochemical Equivalence of Cry3Bb1.11098 and NPTII Proteins in Com Event MON 863 to Microbial Sources. MSL-17220	454240-05	Monsanto Compan	ıy OWN	f <sup>1</sup> roduct Characterization
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Ma	1 .	

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	on, DC 20460. Do not send the form to this address.	ATA MATRIX			
Datc: June 1, 2011				EPA Reg. No./File Symbol: 524-551	Page 38 of 66
Applicant's/Registrant's Name &	Address: N. Lindbergh Blvd., St. Louis, MO 63167			Product: MON 88017	
ingredient B.t. Cry3Bb1 pro	tein and the genetic material (vector ZMIR39) necessary	for its production is	n event MON 88017 com (C	DECD Unique Identifier: MON-886	ð17-3)
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Supplemental Information for "Molecular Analysis of YieldGard* Rootworm/Roundup Ready* Corn Event MON 88017" (MRID No. 461817-02)	465783-01	Monsanto Compa	iny OWN	Product Characterization
860.1340	D. Kolwyck, B-P. Tonnu, Y. A. Dudin, T. Hocsser and K. Gustafson (2001). Validated Method for Extraction and Direct ELISA Analysis of Cry3Bb1 in Cont Grain. Monsanto Ref. No. 99-640E-1.	453731-01	Мопѕаню Сотра	any OWN	Product Characterization
N/A	Astwoorl, JD., R. E. Hileman, M. J. McKee, T. J. Rydel, J. W. Scale and L. English (2001). Safety Assessment of Cry3Bb1 Variants in Corn Rootworm Protected Corn. MSL-17225	454240-09	Monsanto Сотърг	nny OWN	Human Health Assessment
885.1100	Hileman, R. E., J. N. Leach and J. D. Astwood (2001). Assessment of the <i>in vitro</i> Digestibility of Cry3Bb1,11098(Q349R) Protein in Simulated Intestinal Fluid. MSL-17530	455770-02	Monsanto Compa	ıny OWN	Human Health Assessment
885.1100	Holleshak, G., R. E. Hileman and J. D. Astwood (2001). Amended Report for MSL-16597: Immunodetectability of Cry3Bb1.11098 and Cry3Bb1.11231 Proteins in the Grain of Insect Protected Com Events MON 863 and MON 853 After Heat Treatment. MSL-17223	454240-07	Monsanto Comp	any OWN	Human Health Assessment
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs M	Date June 1, 2011 fanager	

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	D/	ATA MATRIX			
Date: June 1, 2011				EPA Reg. No./File Symbol: 524-5	51 Page 39 of 66
	N. Lindbergh Blvd., St. Lonis, MO 63167			Product: MON 88017	
Ingredient B.t. Cry3Bb1 pro Guideline Reference Number	tein and the genetic material (vector ZMIR39) necessary foundation Study Name	for its production in MRID Number	event MON 88017 corn (	OECD Unique Identifier: MON-	88Ø17-3) Note
Guideline Reference Number	Guigerme Study Name	WKID Number	Submitter	Status	Note
885.3050	Beehtel, C. L. (1999). Acute Oral Toxicity of B.r. Protein 11231 in Mice. MSL-16216.	449043-05	Monsanto Comp	any OWN	Humait Health Assessment
885,1100	Hileman, R. E., E. A. Rice, R. E. Goodman and J. D. Astwood (2001). Bioinformatics Evaluation of the Cry3Bb1 Protein Produced in MON 863 Utilizing Allergen, Toxin and Public Oontain Protein Databases. MSL-17140	454240-08	Монзарто Сотр	aliy OWN	Human Health Assessment
885.3050	Bonnette, K. L. and P. D. Pyla (2001). An Acute Oral Toxicity Study in Mice with E. coli Produced Cry3Bb1.11098(Q349R) Protein, Amended Final Report. MSL-17382	455382-02	Monsanto Comp	any OWN	Human Health Assessment
885,1100	Leach, J. N., R. E. Hileman and J. D. Astwood (2001). Assessment of the <i>in vitro</i> Digestibility of Cry3Bb1 Protein Purified from MON 863 and Cry3Bb1 Protein Purified from E. coli. MSL-17292	455382-03	Молянию Сонгр	any OWN	Human Health Assessment
885,3050 Signature	Bechtel, C. L. (1999). Acute Oral toxicity of B.r. Protein 11098 in Mice. MSL-16215  See Page I for Signature	449043-06	Monsante Comp Name and Title J. Austin Burns, Ph.D. Regulatory Affairs M	Date June 1, 2011	Human Health Assessment

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Date: June 1, 2011				EPA Rcg. No./File Symbol; 524-551	Page 40 of 66
Applicant's/Registrant's Name & Monsanto Company, 800 N	Address: N. Lindbergh Blvd., St. Louis, MO 63167			Product: MON 88017	
Ingredient B.t. Cry3Bb1 prot	tein and the genetic material (vector ZMIR39) necessary f	for its production in	event MON 88017 com (	OECD Unique Identifier: MON-880	Ø17-3)
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Hileman, R. E. and J. D. Astwood (1999). Bioinformatics Analysis of B.t. Protein 11098 and B.t. Protein 11231 Sequences Utilizing Toxin and Public Domain Genetic Databases. MSL-15870	449043-08	Monsanto Comp	aity OWN	Human Health Assessment
885.1100	Hileman, R. E. and J. D. Astwood (1999). Bioinformatics Analysis of B.r. Protein 11098 and B.r. Protein 11231 Sequences Utilizing an Allergen Database. MSL-15873	449043-09	Monsanto Comp	any OWN	Human Health Assessment
885.1100	Leach, J. N., R. E. Hileman, J. W. Martin, R. S. Thoma, and J. D. Astwood (2001). Amended Report for MSL-15704: Assessment of the <i>In Vitro</i> Digestibility of <i>B.t.</i> protein 11098 and <i>B.t.</i> 11231 Utilizing Mammalian Digestive Fate Models. MSL-17166	454240-06	Monsanto Comp	auy OWN	Human Health Assessment
885.4200	McKec, M. J. (2001). Bluegill Dictary Toxicity Study for the Bacillus thuringiensis Cry3Bb1 Protein Variant; A Waiver Request. MSL-17383	455382-00	Monsanto Comp	ally OWN	Environmental Assessment
885.4240 Series 72, Subdivision E	Drottar, K. R. and H. O. Krueger (1999). Bacillus thuringiensis Protein 11098 in Corn Pollen: 48-Hour Stalie Renewal Acute Toxicity Test with the Cladoceran (Daphnia magna). MSL-16163	449043-18	Monsanto Comp	any OWN	Environmental Assessment
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs M	Date June 1, 2011 Manager	

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Date: June 1, 2011			EPA I	Reg. No./File Symbol: 524-551	Page 41 of 66
Applicant's/Registrant's Name &		· · · · · · · · · · · · · · · · · · ·			<u>l</u> <del></del>
	N. Lindbergh Blvd., St. Louis, MO 63167			et: MON 88017	
Ingredient B.t. Cry3Bb1 pro	lein and the genetic material (vector ZMIR39) necessary	for its production in	event MON 88017 com (OECI	Unique Identifier: MON-88Ø	17-3)
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4280	Results of acute toxicity tests with <i>Daphnta</i> and carfish did not produce any evidence of adverse effects.  Estuarine and Marine animal studies are waived for this product because of the very low to no potential for exposure to Cry3Bb1 protein from field corn.	N/A	Monsanto Company	OWN	Environmental Assessment Waived in BRAD
885,4340	Texicra, D. (2005). Evaluation of Dietary Effects of a Cry3Bbt Protein Variant on Minute Pirate Bugs ( <i>Orius insidiosus</i> ). MSL-19697	464799-05	Monsanto Company	OWN	Environmental Assessment
885.4300	Since the active ingredient in this product is an insect toxin (Bt endotoxin) that has never shown any toxicity to aquatic or terrestrial plants, these studies have been waived for this product. The Agency has determined there is no significant risk of gene capture and expression of Cry3Bb1 protein by wild or weedy relatives of corn.	Ŋ/A	Monsaulo Company	OWN	Euvironmental Assessment Waived in BRAD
885.4340	Palmer, S. J. and H. O. Krueger (1999). Bacillus thuringiensis Protein 11231: Dietary Toxicity Study with the Ladybird Beetle (Hippodamia convergens). MSL-16166	449043-14	Monsanto Company	OWN	Euvironmental Assessment
850.6200	Hoxter, K. A., S. J. Palmer and H. O. Krueger (1999).  Bacillus thuriagiensis Protein 11231: An Acute Toxicity Study with Earthworm in an Artificial Soil Substrate.  MSL-16162	449043-16	Mousanto Company	OWN	Euvironmental Assessment
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Pl.D. Regulatory Affairs Manag	Date June 1, 2011 ger	

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Date: June 1, 2011			EPA Reg.	No./File Symbol: 524-551	Page 42 of 66
Applicant's/Registrant's Name &				36 ALLANDA CONTROL VALUE POR CARDO	· · · · · · · · · · · · · · · · · · ·
	N. Lindbergh Blvd., St. Louis, MO 63167			MON 88017	
Ingredient B.t. Cry3Bb1 pro	tein and the genetic material (vector ZMIR39) necessary	for its production in	event MON 88017 corn (OECD Un	ique Identifier: MON-880	17-3)
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Teixeira, D. (1999). Assessment of Chronic Toxicity of Corn Tissue Containing the <i>Bacillus thuringiensts</i> Protein 11098 to Collembola (Folsomia candida). MSL-15988	449043-17	Monsanto Conipany	OWN	Environmental Assessment
885.4340	Palmer, S. J. and H. O. Krueger (1999). Bacillus fluringiensis Protein 11231: A Dictary Study with Green Lacewing Larvae (Chrysoperla carnea). MSL-16165	449043-12	Monsanto Company	OWN	Environmental Assessment
885.4340	Palmer, S. J. and H. D. Krueger (1999). Bacillus thuringiensis Protein 11231: A Dictary Study with the Parasitic Hymenoptera (Nasovia vitripennis). MSL-16167	449043-13	Monsanto Company	OWN	Environmental Assessment
885.5200	Dubelman, S., M. Bhatti, B. Ayden, J. Murphy, S. Levine and C. Jiang (2005). Environmental Fate of Cry3Bb1 Protein in Com Fields Planted with MON 863. MSL- 19285	465103-01	Monsanto Company	OWN	Environmental Assessment
885.4340	Duan, J. I., G. Head, M. McKee and T. E. Nickson (2001). Dictary Effects of Transgenic Bacillus flurringiensis (Bt) Com Pollen Expressing a Variant of Cry3Bb1 Protein on Adults of the Ladybird Beetle, Coleomegilla maculata. MSL-16936	453613-01	Monsauto Company	OWN	Environmental Assessment
Signature	See Page 1 for Signature	-	Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date June 1, 2011	-

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Date: June 1, 2011				EPA Reg. No./File Symbol: 524-551	Page 43 of 66
Applicant's/Registrant's Name &					
	N. Lindbergh Blvd., St. Louis, MO 63167			Product: MON 88017	
Ingredient B.t. Cry3Bb1 pro	tein and the genetic material (vector ZMIR39) necessary f	or its production in	event MON 88017 corn (C	DECD Unique Identifier: MON-88Ø	17-3)
Guirleline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Bryan, R. L., J. R. Porch and H. O. Krueger (2001). Dictary Effects of Transgenic BT Com Pollen Expressing a Variant of Cry3Bb1 Protein on the Ladybird Beetle, Hipppdannta convergens. MSL-17171	453613-02	Monsanto Compa	ııy OWN	Environmental Assessment
154-3500	Bhatti, M. A., C. L. Pilcher, M. J. McKee, T. E. Niekson, G. P. Head and C. D. Pilcher (2001). Field Evaluation for the Ecological Impact of Corn Rootworm Insect-Protected Com on Non-Target Organisms. MSL-17179	455382-06	Monsaitto Compa	ny OWN	Environmental Assessment
885.4340	Duan, J. I., M. J. McKee and T. E. Nickson (2001). Dictary Effects of Transgenic Bacillus thuringiensis (Bt) Corn Pollen Expressing a Variant of Cry3Bb1 Protein on Larvae of the Ladybird Beetle, Coleomegilla maculata, MSL-16907	455382-04	Monsanto Compa	ny OWN	Environmental Assessment
885,4340	Scars, M. and M. Mattila (2002). Determination of the Toxicity of Com Pollen Expressing a Cry3Bb1 Variant Protein to First Instar Monarch Butterfly Larvac (Danus plexippus) via Laboratory Bioassay. MSL-17235	455382-05	Monsanto Compa	my OWN	Environmental Assessment
N/A	Head, G., M. Pleau, S. Sivansupramanian and T. Vaughn (2001). Insecticidal Spectrum of Activity for Cry3Bb Protein in vitro. C3NTO	455382-07	Monsanto Compa	uny OWN	Environmental Assessment
Signature	See Page 1 for Signature	b) Selection	Name and Title J. Austin Burns, Ph.D. Regulatory Affairs M	Date June 1, 2011 lanager	

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Applicant's/Registrant's Name &						
	N. Lindbergh Blvd., St. Louis, MO 63167			MON 88017		
Ingredient B.t. Cry3Bb1 pro	tein and the genetic material (vector ZMIR39) necessary	for its production in	event MON 88017 corn (OECD Un	que Identifier: MON-8801	7-3)	
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note	
N/A	Duan, J. J., M. J. McKee, G. Head and C. R. Brown (2002). Endangered Species Impact Assessment for Cry3Bb1 Protein in Transgenic MON 863. MSL-17614	455770-03	Monsauto Company	OWN	Environmental Assessment	
154-2300	Head, G. (2002). Research on the Effects of Com Rootworm Protected Transgenic Com Events on Nontarget Organisms; Preliminary Results. Monsanto Reference No. 00-CR-032E-7	456530-03	Monsanto Company	own	Environmental Assessment	
154-3500	Bhatti, M. A., J. D. Duart, C. L. Pilcher, M. J. McKee, T. E. Nickson, Gr. P. Head and C. Jiang (2002). Ecological Assessment of Nontarget Organisms in the Plots of Com Rootworm Insect Protected Com Hybrid Containing MON 863 Event; 2000 - 2001 Field Trials. Report MSL-17531	4579 <u>16</u> -01	Monsanto Company	OWN	Environmental Assessment	
850.6200	Sindermann, A. B., J. R. Porch and H. O. Krueger (2002). Evaluation of a Cry3Bb1 Protein Variant in an Acute Toxicity Study with the Earthworn in an Artificial Soil Substrate. MSL-18137	457571-01	Monsanto Company	OWN	Environmental Assessment	
885.4050	Gallagher, S. P., J. Grimes and J. B. Beavers (1999).  Bacillus thuringiensis Protein 11231 in Com Grain: A Dietary Toxicity Study with the Northern Bobwlite.  MSL-16161	449043-15	Monsanto Company	own	Environmental Assessment	
Signature	See Page 1 for Signature	550000 Vision 1000	Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date June 1, 2011		

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	pplicant's/Registrant's Name & Adriress: Ionsanto Company, 800 N. Lindbergh Blvd., St. Louis, M <b>O</b> 63167			Product: MON 88017		
Ingredient B.t. Cry3Bb1 pro	tein and the genetic material (vector ZMIR39) necessary	for its production in	event MON 88017 corn	(OECD Uniq	ue Identifier: MON-88Ø t	7-3)
Guidetine Reference Number	Guideline Study Name	MRID Number	Submitter		Status	Note
885.4380	Maggi, V. L. (1999). Evaluation of the Dictary Effect(s) of Purified <i>Bacillus thuringiensis</i> Protein 11231 on Adult Honey Bees ( <i>Apis mellifera</i> L.). MSL-16169	449043-11	Monsanio Com	рану	OWN	Environmental Assessment
885.5200	Martin, J. W., M. J. McKee, S. Dubelman and Y. A. Dudin (2000). Acrobic Soit Degradation of the B.r. Protein 11098 as a Component of Insect Protected Corn. MSL-16440	451568-04	Monsanto Com	pany	OWN	Environmentat Assessment
885,5200	Dubelman, S., B. Ayden, M. Mueth, J. A. Warren, C. Jiang, J. Bookout and Y. Dudin (2002). Acrobic Soil Degradation of the <i>Bacillus thuringiensis</i> Cry3Bbl Variant Protein Produced in Corn Rootworm Protected MON 863. MSL-17102	457571-02	Monsanto Com	pany	OWN	Environmental Assessment
885.4050	George, B. (2001). Comparison of Broiler Performance When Fed Diets Containing Events MON 863, Parental Line or Commercial Corn. MSL-17243	459415-01	Monsaiito Com	pany	OWN	Environmental Assessment
885.4380	Maggi, V.L. (1999). Evaluation of the Dictary Effects of Purified <i>Bacillus thuringiensis</i> Protein 11231 on Honey Bee Larvae. MSL-t6168	449043-10	Monsanto Coni	рану	OWN	Environmental Assessment
885,5200	Dibelman, S., B. Ayden, J. Colyer, B. Ledesma, S. Levine, F. Lloyd, G. Muetler, J. Warren & C. Jiang (2007) Envirormental Fate of the Cry3Bb1 and Cry1Ab Proteins in Com Fields Planted with MON 863 x MON 810 for Three Consecutive Years MSL-20589	472829-02	Monsanto Com	pany	OWN	Environmental Assessment
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D Regulatory Affairs		Date June 1, 2011	

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Applicant's/Registrant's Name &	Address: N. Lindbergh Blvd., St. Louis, MO 63167			ı: MON 88017	
The state of the s	tein and the genetic material (vector ZMIR39) necessary f	or its production in	event MON 88017 corn (OECD	Unique Identifier: MON-88Ø1	7-3)
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
154-3500	Duan, J., M. Bhatti, C. Brown, G. Head, C. Jiang, C. Pilcher, C. Pilcher, D. Carson & T. Nickson (2007) Two Year Pield Assessment of the Effect of Combined Trait Bt Com Mon 863 x MON 810. MSL-19696	472 <u>8</u> 29-01	Monsanto Compuny	_ own	Environmental Assessment
t54-3500	Duan J.J., C. Jiang, M.J. McKee, M.A. Nemeth, D. Ward, G. Head, S. Levine, M. Bhatti and M. Paradise (2004). Statistical Power Analysis of a Two-Year Field Study Evaluating the Ecological Effect of Com Event MON 863. MSL-19246	462627-03	Monsanto Company	own	Environmental Assessment
154-3500	Duan J. J., C. Jiang, C. Brown, M. Bhatti, M. Nemeth, T. Nickson and D. Ward (2004). Supplemental Statistical Analysis of Data from a Two-Year Field Census Study with Com Event MON 863. MSL-19329	463942-02	Monsanto Company	OWN	Environmental Assessment
885.5200	Dubelman S., M. Bhatti and B. Ayden (2004). Interim Report: Assessment of the Environmental Fate of the Cry3Bb1 Protein in Corn Fields Planted with MON 863. MSL-18931	462001-01	Monsauto Company	own	Environmental Assessment
885.4340	Duan J. and M. Paradise (2005). Evaluation of Dietary Effects of Cry3Bb1 Protein on the Ground Beetle Poecihis choleires (Colecoptera:Carabidae). MSL-19631	464799-04	Monsanto Company	OWN	Environmental Assessment
154-3500	Head, G. (2004). Research on the Effects of Com Rootworm Protected Transgenic Corn on Non-Target Organisms: Publications & Manuscripts.	462627-02	Monsanto Company	OWN	Environmental Assessment
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manage	Date June 1, 2011	

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Date: June 1, 2011			EPA R	eg. No./File Symbol: 524-551	Page 47 of 66
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Ingredient B.I. Cry3Bb1 pro	tein and the genetic material (vector ZMIR39) necessary	for its production in	event MON 88017 corn (OECD	Unique Identifier: MON-88Ø	17-3)
Carideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4150	Maminatian wildlife exposure to Cry3Bb1 protein is considered likely; however, the Cry3Bb1 toxicity data for Human Health Assessment indicate that there is no significant toxicity to rodents form testing at the maximum hazard dose. Therefore no hazard to mammalian wildlife is anticipated.	N/A	Монѕалю Сонирану	OWN	Environmental Assessment Waived in BRAD
885.4200	Li, M. H. and E. H. Robinson (1999). Evaluation of Insect Protected Corn Lines MON 853 and MON 859 as a Feed Ingredient for Catfish. MSL-16164	449043-19	Monsanto Company	OWN	Environmental Assessment
885.4340	Duan, J. J., G. Head, M. J. McKee and D. P. Ward (2003). Oata Waiver Request: Toxicity of B.t. Cry3Bb1 Protein in the Red Milkweed Beetle ( <i>Tetraopes</i> sp.). MSI-18741	N/A	Monsanto Company	OWN	Environmental Assessment Granted in BRAE
N/A	Pilcher, C. D. (2001). Efficacy of MON 863 Against Corn Rootworm and Comparison to Insecticide Treatments – Results of Year 2000 Field Trials. Monsauto Ref. No. 00-CR-032E-3	453613-03	Monsanto Company	OWN	Benefits
N/A	Mitchell, P. D. (2002). Yield Benefit of MON 863. MSL-17782	456530-02	Monsanto Company	own	Benefits
Signature	See Page 1 for Signature	***************************************	Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manage	Date June 1, 2011	

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DATA MATRIX Date: June 1, 2011 Page 48 of 66 EPA Reg. No./File Symbol: 524-551 Applicant's/Registrant's Name & Address; Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167 Product: MON 88017 Ingredient B,t, Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3) Guideline Reference Number Guideline Study Name MRID Number Submitter Status Note Ward, D. P. (2002). Public Interest Assessment Supporting Registration of Bacillus thuringiensis Cry3Bbl Protein and the Genetic Material (Vector ZMIR (3L) Necessary for its Production in MON 863. 456530-01 Monsanto Company OWN Benefits N/A MSL-17766 Miller, D. (2000). Public Interest Document Supporting the Registration and Exemption from the Requirement of a Tolerance for the Plant-Incorporated Protectant, Bacillus thuringiensis Cry3Bb Protein, and the Genetic Material Necessary for its Production in Com (Vectors ZMtR12L, ZMIR13L and ZMIR14L). Monsanto Ref. OWN Benefits N/A No. 99-781E 450297-01 Monsanto Company Alston, J. M., J. Hyde and M. C. Marra (2002). An Ex Ante Analysis of the Benefits from the Adoption of Monsanto's Corn Rootworm Resistant Varietal OWN Technology - YieldGard® Rootworm, MSL-17993 Benefits N/A 456923-01 Monsanto Company Vaughn, T. T., M. Pleau, R. Knutson and T. Coombe (2001). Comparing the Efficacy of MON 853 and MON 863 to Three Corn Rootworm Species, Northern Corn Rootworm (Diabrotica barberi), Southern Corn Rootworm (D. undecimpunctata howmdi), and Western N/A Corn Roolworm (D. virgifera virgifera), MTC RPT4 455382-08 OWN Benefits Monsanto Company Vaughn, T., D. Ward, J. Pershing, G. Head and J. McFcrson (2001). An Interim Insect Resistance Management Plan for MON 863: A Transgenic Corn Benefits/IRM N/A Rootworm Control Product. MSL-17556 455770-01 Monsanto Company OWN Date Signature Name and Title June 1, 2011 See Page 1 for Signature J. Austin Burns, Ph.D. Regulatory Affairs Manager

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Applicant's/Registrant's Name & Monsanto Company, 800 N	Address: N. Lindbergh Blvd., St. Louis, MO 63167			Product: M		
Ingredient B.t. Cry3Bb1 prot	ein and the genetic material (vector ZMIR39) necessary t	or its production in	event MON 88017 corn (	OECD Uniqu	e Identifier; MON-88Ø1	7-3)
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter		Status	Note
N/A	Vaughn, T. [2004]. Progress Report on Insect Resistance Management for Corn Event MON 863.	461865-01	Monsauto Comp	pany	OWN	IRM
N/A	Vaughn, T. (2001). Preliminary Results of Research on Insect Resistance Management for a Transgenic Com Rootworm Control Product.	453484-01	Mousanto Com	nany	OWN	IRM
N/A	Hearl, G. and K. Reding. [2006]. Corn rootworm Insect Resistance Management Research [fourteen journal publications)	467424-01	Mousante Com	oany	own	IRM
N/A	Davis, P., G. Head, J. McFerson et. at. (2000). Insect Resistance Management for a Transgenic Com Rootworm Contrnt Product.	451568-05	Monsanto Cong	oany	OWN	IRM
N/A	Vaughn, T. (2003). Estimating Cry3Bb1 Resistance Allele Frequencies in Corn Rootworm Larvac Feeding on MON 863. Monsanto Ref. No. 03-CR-097E-4	459438-01	Monsanto Com	pany	OWN	IRM
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Ingredient B.t. Cry3Bb1 pro	tein and the genetic material (vector ZMIR39) necessary f	or its production in	event MON 880f7 corn (Ol	ECD Unique fdentifier: MON-88Ø	7-3)
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	T. Vaughn (2005), Second Progress Report on Insect Resistance Management for Corn Event MON 863, REVISED	N/A	Монзанто Сотран	y OWN	IRM
N/A	Letter submitted May 23, 2003 to EPA with 12 research protocols on the biology and ecology of the comprootworm pest complex.	N/A	Monsanto Compan	y OWN	IRM
N/A	Vanglin, T. (2004). 2004 Progress Report for the Corn Event MON 863 Resistance Monitoring Program.	462627-01	Монѕанто Сотрап	y OWN	IRM
N/A	Administrative Materials in Support of the Registration of Bacillus thuringiensis Cry3Bb Protein and the Genetic Material (Vector ZMIR13L) Necessary for its Production in Corn; and Amendment of the Previous Request for Exemption from the Requirement of a Tolerance, PP7F4888	451568-00	Monsanto Compan	y OWN	Tolerance Exemption
N/A	Pilacinski, W. P. and M. W. Taylor (1999).  Administrative Materials in Support of the Registration of the Plant-Expressed Protectant Bacillus thuringiensis.  Com Rootworm Control Protein, as Produced in the Cont (Zea mayx, L.), and the Amendanent to the Previous Request for Exemption from the Requirement of a Tolerance, PP7F4888	449043-00	Monsanto Coinpai	ıy OWN	Tolerance Exemption
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	N. Lindbergh Blvd., St. Louis, MO 63167			roduct: MON 88017	
	tein and the genetic material (vector ZMIR39) necessary		T		
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	Petition for Exemption from the Requirement of a Tolerance for <i>Bacillus thuringiensis</i> Cry1, Cry2, and Cry3 Classes of Proteins and the Genetic Material Necessary for the Production of These Proteins in or On All Raw Agricultural Commodities When used as Plant-Pesticide Active Ingredients.	PP 7F4888	Monsanto Compan	y OWN	Tolerance Exemption
885.1100	McCoy, R. L. and A. Sivanovich (2003). Bioinformatics Analysis of the CP4 EPSPS Protein Utilizing the AD4, TOXINS and ALLPEPTIDES Databases. MSL18752	466361-01	Monsanto Compan	y OWN	Inert Ingredient
885.1100	McCoy, R.L. and A. Siyanovich (2005), Updated Bioinformatics Evaluation of the CP4 EPSPS Protein Utilizing the AD5 Database, MSL19894	466361-02	Monsauto Compan	y OWN	Inert Ingredient
885.3050	Monsanto Company (1995). Submission of Toxicology Data in Support of a Tolerance Petition for CP4 EPSPS as a Plant Pesticide Formulation Inert Ingredient: Transmittal of I Study.	436919-00	Monsanto Compan	y Own	lnert Ingredient
885.3050	Harrison, L., M. Bailey, D. Nida, M. Taylor, L. Holden and S. Padgette (1993). Preparation and Confirmation of Doses for an Acute Mouse Feeding Study With CP4 EPSPS. Lab Project Numbers: 92-01-30-12: 92-419-719	436919-01	Monsanto Compan	y OWN	Inert Ingredient
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Ma	Date June 1, 2011	

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Date: June 1, 2011			EPA R	eg. No./File Symbol: 524-551	Page 52 of 66
Applicant's/Registrant's Name & Monsanto Company, 800 l	Address: N. Lindbergh Blvd., St. Louis, MO 63167	***************************************	Deadys	: MON 88017	
	tein and the genetic material (vector ZM1R39) necessary i	for its production in			7-3)
Guideline Reference Number	Guideline Study Name	MRID Number	Subntitter	Status	Note
885.1100	Padgette, S., G. Barry, D. Re, D. Eighholtz, M. Weldon, K. Kolacz and G. Kishore (1993). Purification, Cloning, and Characterization of a Highly Glyphosate-Tolerant 5-enolpyruvylshikimate-3-phosphate Synthase from Agrobocrerinot sp. Strain CP4. MSL-12738	438076-01	Молѕилю Согррапу	own	lnert lugredient
885.1100	Bishop, B. (1993). Production of CP4 EPSP in a 100 Liter Recombinant Ercherichia coli Fermentation. MSL- 12389	438076-02	Monsanto Company	OWN	lucrt Ingredient
885.1100	Hecren, R., S. Padgette and M. Gustafson (1993). The Purification of Recombinant Escherichia coli CP4 5-enolypyruvylshikimate-3-phosphate synthase for Equivalence Studies. MSL-12574	438076-03	Monsanto Company	OWN	Inert Ingredient
<u>N/A</u>	Monsanto Company (1995). Submission of Product Chemistry, Toxicology and Pesticide Fate in Animals Oata in Support of the Exemption for the Requirement of a Petition for Tolerance for CP4 EPSPS, Transmittal of 4 studies.	436433-00	Monsanto Company	OWN	Inert Ingredient
885.1100	Harrison, L., M. Bailey, R. Leimgruber, C. Smith, D. Nida, M. Taylor, M. Gustafson, B. Heeren and S. Padgette (1993). Characterization of Microbially-Expressed Protein; CP4 EPSPS. Lab Project Number: 92/01/30/14: 12901	436433-01	Монѕапто Соптрану	OWN	Inert Ingredient
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manage	Date June 1, 2011	

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	D/	ATA MATRIX			
Date: June 1, 2011			EP	A Reg. No./File Symbol: 524-551	Page 53 of 66
Applicant's/Registrant's Name & Monsanto Company, 800 l	Address: N. Lindbergh Blvd., St. Louis, MO 63167			oduct: MON 88017	
Ingredient B.t. Cry3Bb1 pro	tein and the genetic material (vector ZMIR39) necessary	for its production in	event MON 88017 com (OE	CD Unique Identifier: MON-88@	117-3)
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Lee, T., M. Bailey, C. Smith, J. Zeng, E. Elswick and P. Sanders (1995). Assessment of the Equivalence of CP4 EPSPS Protein Produced in <i>Escherichia coli</i> and European Corn Borer Resistant Com. Lab Project Number: 94-01-39-10; MSL-13920	436433-02	Monsanto Company	OWN	Inert Ingredient
885,3050	Naylor, M. (1993). Acute Oral Toxicity Study of CP4 EPSPS in Albino Mice. Lab Project Number: 92223	436433-03	Monsanto Company	OWN	Inert Ingredient
885.1100	Ream, J., M. Bailey, J. Leach and S. Patigette (1993). Assessment of the in vitro Digestive Fate of CP4 EPSPS Synthase. Lab Project Number: 92-01-30-15: 12949	4364 <u>33</u> -04	Monsanto Company	OWN	lnert Ingredient
N/A	Revisions and Clarification to the Terms & Conditions of Registration for Com Event MON 863 and YieldGard® Plus Corn; Progress Report on Multiple 1RM-Related Activities for MON 863; and Response to EPA Letter Dated August 13, 2004. Submitted 7/7/2005.	N/A	Monsanto Company	OWN	Tenns & Contlitions
NĮĄ	Siegfried, B. and T. Spencer (2005). Susceptibility of Neonate Rootworm Larvae to the Cry3Bb1 Toxin from Bocillus thuringinesis. This report satisfies the Insect Monitoring Terms & Conditions.	467259-01	Monsanto Company		Terms & Conditions
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Man	Date June 1, 2011	

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Date: June 1, 2011				EPA Reg. No./File Symbol: 68467-5	Page 54 of 66
	N. Lindbergh Blvd., St. Louis, MO 63167		1	Product: Herculex® RW Insect P.	
Ingredient <i>B.t.</i> Cry34Ab1 a 59122-7)	nd Cry35Ab1 Insecticidal Crystal protein and the genetic	material necessary f	for its production (plasmid i	nsert PHP17662) in corn (OECD Ide	ntifier: DAS-
Guideline Reference Number	Guideline Study Name	MRID Nuraber	Submitter	Stanis	Note
	Product choracterization data for Bacillus thuringiensis PS 14981 13.6 kDa and 43.8 kDa insecticidal crystal proteins expressed in transgenic maize plants	45242201	68467	PER	
	Equivalency of microbial and maize-expressed PS149B1 proteins	45242203	68467	per	
	Microbial PS149B1 Binary Delta-Endotoxin: Maize- Insect-Pest Susceptibility Study	45242204	68467	PER	
	Comparison of the Amino Acid Sequence of the Bacillus thuringiensis Strain PS 149B1 13.6 kDa and 43.8 kDa Insecticidal Crystal Proteins to Known Protein Allergens	45242205	68467	PER	
	Characterization of <i>Pseudomonas</i> produced and transgenic maize expressed phosphinothricin acetyltransferase (PAT) protein	45242206	68467	PER	
	PS149B1 14 KDA Protein: Acute Oral Toxicity Study în CD-1 Mice	45242207	68467	PER	
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Mana	Date June 1, 2011	35 50 500

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		ATA MATRIX			
Date: June 1, 2011 Applicant's/Registrant's Nome & Monsanto Company 800 l	Address: N. Lindbergh Blvd., St. Louis, MO 63167			Rcg. No./File Symbol: 68467-5	Page 55 of 66
	nd Cry35Ab1 Insecticidal Crystal protein and the genetic	material necessary f			
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	PS149B1 44 KDA Protein: Acute Oral Toxicity Study in CD-1 Mice	45242208	68467	PER	
	PS149B1 14 KDA and 44 KDA Proteins; Acute Oral Toxicity study in CD-1 Mice	45 <u>24220</u> 9	68467	PER	
	PS149B1 Binary Insecticidal Crystal Protein: A Dictary Toxicity Study with the Ladybird Beetle	45242210	68467	PER	
	The Tri-Trophic Interaction Between PS149B1 Transformed Maize, Com Leaf Aphid and Ladybird Beetle	45242211	68467	PER	· · · · · · · · · · · · · · · · · · ·
	In Vitro Digestibility of PS149B1 Proteins	45242212	68467	PER	
	Quantitative ELISA analysis of PS149B1 protein expression levels in hybrid and inbred lines of maize event TC5639 (interim report)	45242213	68467	PER	
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date June 1, 2011	

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Date: June 1, 2011			EPA F	leg. No./File Symbol: 68467-5	Page 56 of 66
Applicant's/Registrant's Name & Monsanto Company, 800 i	N. Lindbergh Blvd., St. Louis, MO 63167			et: Herculex® RW Insect	
ngredient <i>B.t.</i> Cry34Ab1 a i9122-7)	nd Cry35Ab1 Insecticidal Crystal protein and the genetic r	naterial necessary f	or its production (plasmid inse <b>n</b>	PHP17662) in com (OECD Ic	lentifier: DAS-
Inideline Reference Number	Guideline Study Name	MRtD Number	Submitter	Status	Note
	Degradation of Microbial Binary PS149B1 Delta- Endatoxin in a Representative Soil from the Mid-Western USA Maize-Grawing Regian	45242214	68467	PER	····
	Product durability plan for transgente maize expressing insecticidal crystal protein from Bacilhus thrumgiensis strain PS14981 during the experimental use period	45242215	68467	PER	
	Field efficacy of PS149B1 maize events against com rootworms	45242216	68467	PER	, <b>, , , , , , , , , , , , , , , , , , </b>
	Microbial PS149B1 Binary Insecticidal Crystal Protein, Pollen Expressing PS149B1 Binary Insecticidal Crystal Protein, and Individual PS149B1 14kDa and 44 kDa Insecticidal Crystal Proteins	45340701	68467	PER	
	Thermolability of PS149B1 Binary Delta-Endoloxin	45358401	68467	PER	
74	PS149B1binary insecticidal crystal protein: Acute toxicity study to the earthworm in an artificial substrate	45360201	68467	PER_	
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, PluD. Regulatory Affairs Manager	Date June 1, 2011	2 14- (54-45

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Date: June 1, 2011				EPA Reg. No./File Symbol: 68467-5	Page 57 of 66
Applicant's/Registrant's Name &					
	N. Lindbergh Blvd., St. Louis, MO 63167			Product: Herculex® RW Insect P	
Ingredient <i>B.t.</i> Cry34Ab1 a 59122-7)	and Cry35Ab1 Insecticidal Crystal protein and the genetic r	naterial necessary t	for its production (plasmi	d insert PHP17662) in com (OECD Ide	ntifier: DAS-
Guideline Reference Number	Guideline Study Nome	MRID Number	Submitter	Status	Note
	Lateral flow test kit method validation for the detection of the PS149B1 14 kDa and 44 kDa protein in maize grain	45383401	68467	PER	
	Heat lability of individual proteins of the PS149B1 binary ICP	45584501	68467	PER	
	tn Vitro Simulated Gastric Fluid Digestibility Study of Microbially Derived Cry34Ab I Protein	45584502	68467	PER	
	Characterization of Cry34Ab1 and Cry35Ab1 from Recombinant Pseudomonas fluorescens and Transgenic Majze	45790401	68467	PER	
	Characterization of DNA Inserted into Transgenic Com Events (Cry34Abt and Cry35Abl)	45790402	68467	PER	
	PS149B1 Binary Insecticidal Crystal Protein: An 8-Day Dietary Study with the Rainbow Trout, Oncorhynchus mykiss, Walbaum	45790403	68467	PER	
	PS149B1 Binary Insecticidal Crystal Protein: An Acute Toxicity Study with the Dophnid, Daphnia magna Straus	45790404	68467	PER	\$155°
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Ma	5.0 Company of the Co	

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Date: June 1, 201 t	20 10 5	\$6. \$4		EPA Rcg. No./File Symbol: 68467-5	Page 58 of 66
Applicant's/Registrant's Name &		\$1_\$/\$			
	N. Lindbergh Blvd., St. Louis, MO 63 (67			Product: Hercitlex® RW Insect	
Ingredient B.t. Cry34Abl a 59122-7)	nd Cry35Ab1 Insceticidal Crystal protein and the genetic n	naterial necessary f	or its production (plasmid	d insert PHP17662) in com (OECD)	Identifier: DAS-
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	PS149B1 Binary tnsecticidal Crystal Protein: Dictary Toxicity to Parasitic Hymenoptern (Nasonia vitripennis)	45790405	68467	PER	
	Assessment of Chronic Toxicity of Diet Containing  Bacillus thuringiensis PS149B1 the three toxicity of Diet Containing  Protein to Collembola (Falsomia canditla)	<b>45</b> 790406	68467	PER	
	PS149B1 Insecticidal Crystal Protein: Dictary Toxicity to Green Lacewing Larvac (Chrysoperla carnea)	45790407	68467	PER	
	SDS-PAGE Sensitivity Analysis for Cry35Ab1 in Support of the Simulated Gastric Fluid Digestion Study MRID#45242212	45790408	68467	PER	
	Trait Durability and Experimental Use of Transgenic Maize Expressing the Insecticidal Crystalline Proteins Cry34Ab1 and Cry35Ab1	45790509	68467	PER	
***	Field Efficacy of Cry34Ab1/Cry35Ab1 Maize Events Agoinst Corn Rootworms	45790410	68467	PER	
	Product characterization data for Bacillus thuringienxis Cry34Ab1 and Cry35Ab1 proteins expressed in transgenic maize plants (PHP 17658)	45790501	68467	PER	35568
	Product Characterization Dato for Bacillus thuringtensis Cry34Ab1 and Cry35Ab1 Proteins Expressed in Transgenic Maize Plants (PHP17662)	45 <u>790</u> 601	68467	PER	
Signature	See Page 1 for Signature		Name and Title J. Austin Bums, Ph.D. Regulatory Affairs Ma		

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Date: June 1, 2011			.0000	EPA Reg. No/Fite Symbot: 68467-5	Page 59 of 66
Applicants/Registrant's Name &					
	N. Lindbergh Blvd., St. Louis, MO 63167			Product: Herculex® RW Insect	
Ingredient <i>B.t.</i> Cry34Ab1 a: 59122-7)	nd Cry35Ab1 Insecticidal Crystal protein and the genetic	naterial necessary i	for its production (plasmic	l insert PHP 17662) in corn (OECD Id	entifier: DAS-
Guidetine Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Summary of Heat Lability Studies will Cry34Ab1/Cry35Ab1	4580860 L	68467	VER	
	Quantilative ELISA analysis of Cry34Ab1 and Cry35Ab1 proteins expressed in maize plants transformed with the vector PHP17658	45833101	68467	PER	
7001	Quantitative ELISA analysis of Cry34Abt and Cry35Abl proteins expressed in maize plants transformed will the vector PHPt7662	45833102	68467	PER	
	Quantitative ELtSA Analysis of Cry34Ab1 and Cry35Abt Proteins Expressed in Majze Plants Transformed with the Vector PHP t7662	45833201	68467	PER	
	Stide Presentation Summarizing Cry34Ab1/Cry35Ab1 teat Inactivation Studies.	45860201	68467	PER	
	Probe MOA studies to assess potential for protein synthesis inhibition by Bacillus thuringieusis PS 149B1 Cry34Ab1/Cry35Ab1 proteins in rabbit reticulocyte assay: Re-examination of lab notebook data	45942801	68467	PER	
	Product characterization data for Bacillus thuringlensis Cry34Abt and Cry35Abl proteins expressed in transgenic maize plants (PtP17662)	4603000 t	68467	PER	<b>.</b>
Section 1988 to 1989	tndependent Laboratory Validation Pioneer Hi-Bred tnternational, tne. ELISA Method for the Quantitification of Cry34Ab1Protein from Transgenie Plants	46123901	68467	PER	
	Independent Laboratory Validation of Dow AgroSciences Method GRM 03.13, "Determination of Cry35Abt Insecticidal Crystat Protein in Maize Tissue by Enzyme- Linked Immunosorbent Assay"	46123902	68467	PER	
Signature	See Page 1 for Signature	22.2.3.3	Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Ma		1201

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Date: June 1, 2011			EPA	Reg. No./File Symbol: 68467-5	Page 60 of 66	
	N. Lindbergh Blvd., St. Louis, MO 63167			uct: Herculex® RW brsect P		
ngredient B.t. Cry34Abl a 9122-7)	nd Cry35Ab1 Insecticidal Crystal protein and the genetic r	naterial necessary t	or its production (plasmid inse	rt PHP17662) in corn (OECD Ide	ntifier: DAS-	
iuideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note	
	Cry34/35 Protein Distribution and Familiarity	46123903	68467	PER		
The state of the s	Agronomic Characteristics, Quantitative ELISA and Nutrient Composition Analysis of Hybrid Maize Lines Containing Cry34Abt, Cry35Abl and PAT Genes: Chile Locations	46123904	68467	PER		
	Biological equivalency of Cry34/35Ab1 insecticidal crystal protein in transgenic plants and derived from transgenic Pseudomonax fluoresceus	46123905	68467	PER		
70	Characterization of Cry34Ab1 and Cry35Abt Proteins Derived from Transgenic Maize event E4497,59.1.22 (DAS-59122-7)	46123906	68467	PER		
-	Characterization of Phosophinothriein Acctyltransferase (PAT) Derived from Transgenic Maize Event E4497.59.1.22	46123907	68467	PER		
	Characterization of DNA Inserted into Transgenic Corn Events DAS-45216-6 and DAS-59122-7	46123908	68467	PER		
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manage	Date June 1, 2011	- 1000	

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Date: June 1, 2011				EPA Reg. No./File Symbol: 68467-5	Page 61 of 66
	N. Lindbergh Blvd., St. Louis, MO 63167			Product: Herculex® RW Insect F	
Ingredient <i>B.t.</i> Cry34Ab1 a 59122-7)	nd Cry35Ab1 Insecticidal Crystal protein and the genetic t	material necessary	for its production (plasmi	d Insert PHP17662) in corn (OECD Ide	entifier: DAS-
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Detailed characterization of DNA inserted into transgenic corn events DAS-45216-6 and DAS-59122-7	46123909	68467	PER	
· · · · · · · · · · · · · · · · · · ·	Evaluation of microbe derived Cry34Abt and Cry35Abl proteins for protein synthesis inhibition activity	46123910	68467	PER	
	Nutritional Equivalency Study of Maize Containing Cry34Abl and Cry35ABl: Poultry Feeding Study	46123911	68467	PER	
	The effect of Cry34Ab1/Cry35Ab1 proteins on the development and mortality of the Ladybird beetle Colemegilla proemlata DeGeer	46123912	68467	PER	
	Non-target Invertebrate Ecological Risk Assessment for Field Corn Expressing Cry34Ab1 and Cry35Ab1 Insecticidal Crystal Proteins in Event DAS-591227	46123913	68467	PER	
	Evaluation of the impact of com rootworm controt strategies on non-target arthropods	46123914	68467	PER	
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Ma		

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Applicant's/Registrant's Name &					
	N. Lindbergh Blvd., St. Louis, MQ 63167			Product: Herculex® RW Insect F	
tngredient <i>B.t.</i> Cry34Ab1 a 59122-7)	nd Cry35Ab1 Insecticidal Crystal protein and the genetic	material necessary f	for its production (plasmid	insert PHP17662) in com (OECD Ide	entifier: DAS-
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Investigations into Dose of Cry34Ab1/Cry35Ab1 ~ Rootworm-Resistant Maize Event DAS-59t22-7 Against Western and northern Corn Rootworms in Support of Trait Durability Plans	46123915	68467	PER	
- And -	Effect on Western Corn Rootworm Adults of Feeding on Cry34/35Ab1-Corn Rootworm Protected Corn Tissue and Implications for Product Durability	46123916	68467	PER	
	Evaluation of endangered/threatened insect species relative to the use of Cry34Ab/Cry35Abl com rootworm-resistant maize hybrids	46123917	68467	PER	
	Trait Durability Plan for Cry34/35 Com Roottvorm Protected corn Event DAS-59122-7 Following Commercialization	46123918	68467	PER	
	Simulations of Corn Rootworm Adaptation to Cry34/35 Corn Rootworm Protected Corn in Support of Trait Durability Plans for Event DAS-59122-7	46123919	68467	PER	
	Digestion of Allergenic and Non-Allergenic Proteins in Simulated Gastrie Fluid	46123920	_68467	PER	
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Ma		

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	on, DC 20460. Do not send the form to this address.  DA	TA MATRIX				
Date: June 1, 2011				EPA Rcg. No./File Symbol: 68467-5	Page 63 of 66	
	N. Lindbergh Blvd., St. Louis, MO 63167	: XDXXX:		Product: Herculex® RW Insect Protection		
Ingredient <i>B.t.</i> Cry34Ab1 a 59122-7)	nd Cry35Abl Insecticidal Crystal protein and the genetic r	material necessary f	for its production (plasmid	insert PHP17662) in corn (OECD Idea	ttifier; DAS-	
Guideline Reference Number	Guideline Study Name	MRtD Number	Submitter	Status	Note	
70	Public Interest Document for Cry34/35Ab1 Com Rootworm-Protected Com	46123921	68467	PER		
19.	Investigation of Potential Interaction between CrylF and the Binary Cry34Ab1/Cry35Ab1 Proteins	46343806	68467	PER		
	Digestion efficiency of altergens and non-attergens in simulated gastric fluid: Bacillus thuringiensis Cry 34/35Ab1 construct PHP17662	4638860t	68467	PER		
THE THE	Lack of Cry34Ab1/Cry35Ab1 co-association in solution	4655680t		PER		
- 104	Evaluation of the Sequence Similarities of the Cry34Ab1, ery35Ab1, and PAT Proteins to the Public Protein Sequence Datasets	4658470t	68467	PER	<u></u>	
	Summary report of a carabid beetle laboratory toxicity study using Cry34Ab1 and Cry35Ab1 including copies of references	467141 <u>D1</u>	68467	PER		
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Mar	Date June 1, 2011		

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

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<u> </u>	D/	ATA MATRIX			
Date: June t, 2011		2333		PA Reg. No/File Symbol: 68467-5	Page 64 of 66
	N. Lindbergh Blvd., St. Louis, MO 63167			Product: Herculex® RW Insect P.	
Ingredient B.r. Cry34Abt a 59122-7)	nd Cry35Ab1 Insecticidal Crystal protein and the genetic	material necessary f	for its production (plasmid i	nsert PHP t7662) in corn (OECD Ide	ntifier: DAS-
Guideline Reference Number	Guideline Study Name	MRtD Number	Submitter	Status	Note
	Preliminary resistance monitoring plan for Cry34/35Abt corn event DAS-59122-7	46769201	68467	PER	
	Detailed resistance monitoring plan for Cry34/35Abt corn event DAS-59122-7	47334201	68467	PER	
	Evaluation of potential dictary effects of Cry34/35Abl protein on insidious flower bugs, Orius insidiosus (Hemiptera: Anthocoridae)	47436701	68467	PÉR	····
	Monitoring com rootworm susceptibility to Cry34/35Ab1 event DAS-59122-7: 2007 insect collections	47522501	68467	PER	
	Three-Year Field Monitoring of Cry34/35Ab1 and Cry1F x Cry34/35Ab1 Maize Hybrids for Nontarget Anhropod Effects	47870301	68467	PER	
	Monitoring com rootworm susceptibility to Cry34/35Ab1 event DAS-59122-7; 2008 insect collections	47900801	68467	PGR	
Signature	See Page 1 for Signature		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Mana	Date June 1, 2011	

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	DA	ATA MATRIX			
Date: June 10, 2011			E	PA Reg. No./File Symbol: 68467-5	Page 65 of 66
	N. Lindbergh Blvd., St. Louis, MO 63167		Pr	oduct: Herculex® RW Insect F	
Ingredient B.t. Cry34Ab1 a 59122-7)	and Cry35Ab1 Insecticidal Crystal protein and the genetic	naterial necessary i	for its production (plasmid in	sert PHP17662) in corn (OECD Ide	ntifier: DAS-
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Soil accumulation of Cry34Ab t and Cry35Ab t proteins after three years of cropping with DAS-59122-7 com	47 <u>959501</u>	68467	PER	
	Investigating Performance of Herculex TMT RW and Herculex TMT XTRA Under Commercial Use	4804550 t	68467	PER	
	Monitoring Com Rootworm Susceptibility to Cry34/35Ab1 Event DAS-59122-7: 2009 Growing Season	48279701	68467	PER	
	2010 Insect Resistance Management Compliance Assurance Program for Com Borer Protected Bt Corn, Com Rootworm Protected Bt Corn, and Com Borer/Com Rootworm-Protected Stacked Bt Corn	48375001	68467	PER	20070
Signature	Sec Page 1 for Signature	200 See 1997	Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manag	Date June 1, 2011	

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# **⊗EPA**

#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of Information Is estimated to average 0.25 hours per response for registration and special review adivities, including time for reading the Instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmentat Protection Agency, 401 M Street S.W. Washington DC 20460. Do not send the form to this address

	D/	ATA MATRIX			
Date: June 10, 20tt			EP	A Reg. No./Fite Symbot: 68467-5	Page 66 of 66
Applicant's/Registrant's Name &					
	N. Lindbergh Blvd., St. Louis, MO 63167 and Cry35Abt Insecticidat Crystat protein and the genetic			duct: Herculex® RW Insect P	
ngredient B.t. Cry34Abt at 59122-7)	nd Cry55Aot Insecticidal Crystal protein and the genetic	material necessary i	or its production (plasmid ins	ert PAP (7002) in com (OBCD foe	nuner, DAS-
Buideline Reference Number	Guidetine Study Name	MRID Number	Submitter	Status	Note
	Enhanced Insect Resistance Management Comptiance Assurance Program for Corn Borer Protected Bt Corn, Corn Rootworm Protected Bt Corn, and Corn Borer/Corn Rootworm-Protected Stacked Bt Corn	4837510t	68467	PER	
	Revised Guidelines for Evaluating Unexpected Com Rootworm Damage in Herculex® RW and Herculex® XTRA	4843070t	68467	PER	
Signature	See Page 1 for Signature	16	Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manag	Date June 1, 2011	

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#### SUMMARY OF THE APPLICATION

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The subject of this application is for the registration extension of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 Insect Protected, Herbicide-Tolerant Corn (Genuity<sup>®</sup> SmartStax<sup>®</sup> RIB Complete<sup>™</sup>; EPA Reg. No. 524-595).

Genuity® SmartStax® RIB Complete™ was conditionally registered on April 8, 2011. The initial time-limited registration expires on October 31, 2011. This current application request is to extend EPA Reg. No. 524-595 for a period of two years beyond the current expiration date based on the EPA's registration decision in the BRAD for this product (EPA Docket ID EPA-HQ-OPP-2011-0362-0002, April 8, 2011; p27). A subsequent registration extension will be requested at that time, based on the revised registration duration scheme for PIP products representing reduced risk for developing insect resistance (Optimum® AcreMax™ B.t. Corn Seed Blends BRAD; August 4, 2010; p19). An updated data matrix is being supplied with this application. With the exception of the revised label to incorporate bag-tag language suitable for both the corn- and cotton-growing areas as required under the current terms and conditions, no other changes are being requested to the registration conditions as part of this registration extension request.

"RIB Complete is a trademark of Monsanto Technology, LLC.

<sup>&</sup>lt;sup>®</sup> Genuity and SmartStax are registered trademarks of Monsanto Technology, LLC.

#### PRODUCT LABEL

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The subject of this application is for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>™</sup>. No substantive changes to the label for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 Insect-Protected, Herbicide-Tolerant Corn in EPA Reg. No. 524-595, as updated April 8, 2011, are being requested. The patent numbers have been updated. Five copies of the proposed label for the registration of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>™</sup> are attached.

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#### Plant-Incorporated Protectant Label

# MON 89034 × TC1507 × MON 88017 × DAS-59122-7

RIB Complete<sup>TM</sup>
Insect-Protected, Herbicide-Tolerant Corn
(Alternate Brand Name: Genuity® SmartStax® RIB Complete<sup>TM</sup>)‡
(OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7)

Active Ingredients:

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Bacillus thuringiensis Cry1A.105 protein and the genetic material (vector PV-ZMIR245) necessary for its production in corn event MON 89034 (OECD Unique Identifier: MON-89Ø34-3)  ≤ 0.0026%*
Bacillus thuringiensis Cry2Ab2 protein and the genetic material (vector PV-ZMIR245) necessary for its production in corn event MON 89034 (OECD Unique Identifier: MON-89034-3) ≤ 0.0053%*
Bacillus thuringiensis Cry1F protein and the genetic material (vector PHP8999) necessary for its production in corn event TC1507 (OECD Unique Identifier: DAS- $\emptyset$ 15 $\emptyset$ 7-1) $\le 0.0012\%$ *
Bacillus thuringiensis Cry3Bb1 protein and the genetic material (vector PV-ZMIR39) necessary for its production in corn event MON 88017 (OECD Unique Identifier: MON-88017-3)
Bacillus thuringiensis Cry34Ab1 protein and the genetic material (vector PHP17662) necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7)≤0.0194%*
Bacillus thuringiensis Cry35Ab1 protein and the genetic material (vector PHP17662) necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7)≤0.0042%*
Other Ingredients: CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) and the genetic material (vector PV-ZMIR39) necessary for its production in corn event MON 88017
PAT protein (phosphinothricin acetyl transferase) and the genetic material (vectors PHP17662 and PHP8999) necessary for its production in corn events TC1507 and DAS-59122-7≤0.00045%* *Maximum percent (wt/wt) of dry forage
‡ Genuity® SmartStax® R1B Complete™ seed with this refuge configuration contains 95% MON 89034 × TC1507 × MON 88017 × DAS-59122-7 mixed with at least 5% non-Bt corn within a single lot of seed.

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#### KEEP OUT OF REACH OF CHILDREN

#### CAUTION

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NET CONTENTS

EPA Registration No. 524-595 EPA Establishment No. 524-MO-002

Monsanto Company 800 North Lindbergh Blvd. St. Louis, MO 63167

#### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. This product must be used as specified in the terms and conditions of the registration.

This product may be combined or produced through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

MON 89034 × TC1507 × MON 88017. × DAS-59122-7 RIB Complete™ protects corn crops from leaf, stalk, and ear damage caused by lepidopteran corn pests listed on this label and root damage caused by corn rootworm larvae listed on this label. In order to minimize the risk of these pests developing resistance to MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ corn, an insect resistance management plan must be implemented as defined in the registration terms and conditions.

Grower agreements will specify that growers must adhere to the refuge requirements that will be described on the bag or bag/tag for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>™</sup> corn or other applicable product use documents.

Sales of corn hybrids that contain Monsanto's Bt corn plant-incorporated pesticide(s) must be accompanied by either an IRM/Grower Guide or information on the bag or bag-tag, on planting, production, and insect resistance management, and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the Bt proteins is planted.

Corn seed bags or bag tags for products containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ must include the refuge size requirement in text and graphical format.

#### INSECT RESISTANCE MANAGEMENT

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Growers are instructed to read information on insect resistance management in the bag and/or bag-tag.

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per plant-incorporated protectant (PIP) active ingredient per registrant per year.

The seed producer must ensure a minimum of 5% non-PIP refuge seed is included with the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 in each lot of seed corn. The refuge seed in the seed mixture may not be treated with seed-applied insecticides for corn rootworm (CRW) control unless the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 seed in the seed mixture receives the same treatment.

The IRM/Grower Guide for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>TM</sup> or comparable information presented on the product bag or bag-tag, must contain the following information:

This product is a seed mixture containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 and a minimum of 5% non-Bt seed that when planted creates an interspersed refuge within the field. There are no requirements for a separate structured refuge for Genuity® SmartStax® RIB Complete™ corn when planted in the U.S. corn-growing region, including Alaska and Hawaii, because the refuge seed is contained within the bag/container.

The interspersed refuge can only be used by planting seed corn specifically generated by qualified seed producers/conditioners licensed by the registrant. Insecticidal treatments labeled for adult CRW control are discouraged during the time of adult CRW emergence.

The seed mix refuge option for Genuity® SmartStax® RIB Complete™ satisfies the refuge requirements in all regions other than in the cotton-growing region where corn earworm is a significant pest as defined below.

#### Additional refuge requirements in the cotton-growing region where corn earworm is a significant pest

In the cotton-growing region where corn earworm is a significant pest, as defined below, Genuity® SmartStax® RIB Complete™ requires the planting of an additional 20% structured refuge (i.e. 20 acres of non-Bt corn for every 80 acres of Genuity® SmartStax® RIB Complete™ planted).

The 20% refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn rootworms or corn borers. The refuge and the Genuity® SmartStax® RIB Complete™ should be sown on the same day, or with the shortest window possible between

Monsanto Company 11-CR-192E-2R planting dates to ensure that corn root development is similar among varieties. The structured refuge may be planted as an in-field or adjacent (e.g., across the road) refuge or planted as a separate block that is within ½ mile of the Genuity® SmartStax® RIB Complete™ field. In-field refuge options include blocks, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The refuge can be protected from lepidopteran damage by use of non-Bt insecticides if the population of one or more target lepidopteran pests of Genuity® SmartStax® RIB Complete™ in the refuge exceeds economic thresholds. In addition, the refuge can be protected from CRW damage by an appropriate seed treatment or soil insecticide; however, insecticides labeled for adult CRW control must be avoided in the refuge during the period of CRW adult emergence. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants).

The cotton-growing region requiring the additional 20% refuge consists of the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).

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#### Corn Insects Controlled or Suppressed

European corn borer (ECB)
Southwestern corn borer (SWCB)
Southern cornstalk borer (SCSB)
Corn earworm (CEW)
Fall armyworm (FAW)
Stalk borer
Lesser corn stalk borer
Sugarcane borer (SCB)
Western bean cutworm (WBC)
Black cutworm

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Western corn rootworm (WCRW) Northern corn rootworm (NCRW) Mexican corn rootworm (MCRW) Ostrinia nubilalis
Diatraea grandiosella
Diatraea crambidoides
Helicoverpa zea
Spodoptera frugiperda
Papaipema nebris
Elasmopalpus lignosellus
Diatraea saccharalis
Richia albicosta
Agrotis ipsilon

Diabrotica virgifera virgifera Diabrotica barberi Diabrotica virgifera zeae

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 is a product of Monsanto's and Dow AgroSciences' research programs, offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents: 5322938, 5352605, 5359142, 5378619, 5424412, 5550318, 5554798, 5641876, 5717084, 5728925, 5804425, 6018100, 6025545, 6051753, 6063597, 6083878, 6331665, 6489542, 6645497, 6713063, 6962705, 7064249, 7070982, 7112665, 7227056, 7250501, 7304206, 7544862, 7618942, 7927598, and RE39247.

EPA Accepted: \_\_/\_/\_

#### Plant-Incorporated Protectant Labet

# MON 89034 × TC1507 × MON 88017 × DAS-59122-7

RIB Complete<sup>TM</sup>
Insect-Protected, Herbicide-Tolerant Corn
(Alternate Brand Name: Genuity® SmartStax® RIB Complete<sup>TM</sup>)‡
(OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7)

Active Ingredients:  Bacillus thuringiensis Cry1A.105 protein and the genetic material (vector PV-ZMIR245)  necessary for its production in corn event MON 89034 (OECD Unique Identifier: MON-89034-3)
Bacillus thuringiensis Cry2Ab2 protein and the genetic material (vector PV-ZMIR245) necessary for its production in corn event MON 89034 (OECD Unique Identifier: MON-89Ø34-3)≤ 0.0053%*
Bacillus thuringiensis Cry1F protein and the genetic material (vector PHP8999) necessary for its production in corn event TC1507 (OECD Unique Identifier: DAS-Ø15Ø7-1) ≤ 0.0012%*
Bacillus thuringiensis Cry3Bb1 protein and the genetic material (vector PV-ZMIR39) necessary for its production in corn event MON 88017 (OECD Unique Identifier: MON-88Ø17-3)≤ 0.0079%*
Bacillus thuringiensis Cry34Ab1 protein and the genetic material (vector PHP17662) necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7)≤ 0.0194%*
Bacillus thuringiensis Cry35Ab1 protein and the genetic material (vector PHP17662) necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7) ≤ 0.0042%*
Other Ingredients: CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) and the genetic material (vector PV-ZMIR39) necessary for its production in corn event MON 88017
PAT protein (phosphinothricin acetyl transferase) and the genetic material (vectors PHP17662 and PHP8999) necessary for its production in corn events TC1507 and DAS-59122-7≤ 0.00045%* *Maximum percent (wt/wt) of dry forage
‡ Genuity® SmartStax® RIB Complete™ seed with this refuge configuration contains 95% MON 89034 × TC1507 × MON 88017 × DAS-59122-7 mixed with at least 5% non-Bt corn within a single lot of seed.

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#### KEEP OUT OF REACH OF CHILDREN

#### CAUTION

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MET	CONTENTS	

EPA Registration No. 524-595 EPA Establishment No. 524-MO-002

Monsanto Company 800 North Lindbergh Blvd. St. Louis, MO 63167

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#### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. This product must be used as specified in the terms and conditions of the registration.

This product may be combined or produced through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>™</sup> protects corn crops from leaf, stalk, and ear damage caused by lepidopteran corn pests listed on this label and root damage caused by corn rootworm larvae listed on this label. In order to minimize the risk of these pests developing resistance to MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>™</sup> corn, an insect resistance management plan must be implemented as defined in the registration terms and conditions.

Grower agreements will specify that growers must adhere to the refuge requirements that will be described on the bag or bag/tag for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>TM</sup> corn or other applicable product use documents.

Sales of corn hybrids that contain Monsanto's Bt corn plant-incorporated pesticide(s) must be accompanied by either an IRM/Grower Guide or information on the bag or bag-tag, on planting, production, and insect resistance management, and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the Bt proteins is planted.

Corn seed bags or bag tags for products containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>TM</sup> must include the refuge size requirement in text and graphical format.

#### INSECT RESISTANCE MANAGEMENT

Growers are instructed to read information on insect resistance management in the bag and/or bag-tag.

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per plant-incorporated protectant (PIP) active ingredient per registrant per year.

The seed producer must ensure a minimum of 5% non-PIP refuge seed is included with the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 in each lot of seed corn. The refuge seed in the seed mixture may not be treated with seed-applied insecticides for corn rootworm (CRW) control unless the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 seed in the seed mixture receives the same treatment.

The IRM/Grower Guide for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>TM</sup> or comparable information presented on the product bag or bag-tag, must contain the following information:

This product is a seed mixture containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 and a minimum of 5% non-Bt seed that when planted creates an interspersed refuge within the field. There are no requirements for a separate structured refuge for Genuity<sup>®</sup> SmartStax<sup>®</sup> RIB Complete<sup>TM</sup> corn when planted in the U.S. corn-growing region, including Alaska and Hawaii, because the refuge seed is contained within the bag/container.

The interspersed refuge can only be used by planting seed corn specifically generated by qualified seed producers/conditioners licensed by the registrant. Insecticidal treatments labeled for adult CRW control are discouraged during the time of adult CRW emergence.

The seed mix refuge option for Genuity<sup>®</sup> SmartStax<sup>®</sup> RIB Complete<sup>™</sup> satisfies the refuge requirements in all regions other than in the cotton-growing region where corn earworm is a significant pest as defined below.

# Additional refuge requirements in the cotton-growing region where corn earworm is a significant pest

In the cotton-growing region where corn earworm is a significant pest, as defined below, Genuity<sup>®</sup> SmartStax<sup>®</sup> RIB Complete<sup>™</sup> requires the planting of an additional 20% structured refuge (i.e. 20 acres of non-Bt corn for every 80 acres of Genuity<sup>®</sup> SmartStax<sup>®</sup> RIB Complete<sup>™</sup> planted).

The 20% refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn rootworms or corn borers. The refuge and the Genuity<sup>®</sup> SmartStax<sup>®</sup> RIB Complete<sup>™</sup> should be sown on the same day, or with the shortest window possible between

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Monsanto Company 11-CR-192E-2R Page 93 of 110 218

planting dates to ensure that corn root development is similar among varieties. The structured refuge may be planted as an in-field or adjacent (e.g., across the road) refuge or planted as a separate block that is within ½ mile of the Genuity® SmartStax® RIB Complete™ field. In-field refuge options include blocks, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The refuge can be protected from lepidopteran damage by use of non-Bt insecticides if the population of one or more target lepidopteran pests of Genuity® SmartStax® RIB Complete™ in the refuge exceeds economic thresholds. In addition, the refuge can be protected from CRW damage by an appropriate seed treatment or soil insecticide; however, insecticides labeled for adult CRW control must be avoided in the refuge during the period of CRW adult emergence. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants).

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The cotton-growing region requiring the additional 20% refuge consists of the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).

#### Corn Insects Controlled or Suppressed

European corn borer (ECB)
Southwestern corn borer (SWCB)
Southern cornstalk borer (SCSB)
Corn earworm (CEW)
Fall armyworm (FAW)
Stalk borer

Lesser corn stalk borer Sugarcane borer (SCB)

Western bean cutworm (WBC)

Black cutworm

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Western corn rootworm (WCRW) Northern corn rootworm (NCRW) Mexican corn rootworm (MCRW) Ostrinia nubilalis
Diatraea grandiosella
Diatraea crambidoides
Helicoverpa zea
Spodoptera frugiperda
Papaipema nebris
Elasmopalpus lignosellus
Diatraea saccharalis
Richia albicosta
Agrotis ipsilon

Diabrotica virgifera virgifera Diabrotica barberi Diabrotica virgifera zeae

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 is a product of Monsanto's and Dow AgroSciences' research programs, offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents: 5322938, 5352605, 5359142, 5378619, 5424412, 5550318, 5554798, 5641876, 5717084, 5728925, 5804425, 6018100, 6025545, 6051753, 6063597, 6083878, 6331665, 6489542, 6645497, 6713063, 6962705, 7064249, 7070982, 7112665, 7227056, 7250501, 7304206, 7544862, 7618942, 7927598, and RE39247.

EPA Accepted: \_/\_/\_

#### Plant-Incorporated Protectant Label

### MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>TM</sup>

Insect-Protected, Herbicide-Tolerant Corn
(Alternate Brand Name: Genuity® SmartStax® RIB Complete™)‡
(OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-1 ×
MON-88Ø17-3 × DAS-59122-7)

MON-08917-3 ^ DA3-39122-7)
Active Ingredients:  Bacillus thuringiensis Cry1 A.105 protein and the genetic material (vector PV-ZMIR245)  necessary for its production in corn event MON 89034 (OECD Unique Identifier: MON-89Ø34-3)  ≤ 0.0026%*
Bacillus thuringiensis Cry2Ab2 protein and the genetic material (vector PV-ZMIR245) necessary for its production in corn event MON 89034 (OECD Unique Identifier: MON-89Ø34-3)≤0.0053%*
Bacillus thuringiensis Cry1F protein and the genetic material (vector PHP8999) necessary for its production in corn event TC1507 (OECD Unique Identifier: DAS- $\emptyset$ 15 $\emptyset$ 7-1) $\le 0.0012\%$ *
Bacillus thuringiensis Cry3Bb1 protein and the genetic material (vector PV-ZMIR39) necessary for its production in corn event MON 88017 (OECD Unique Identifier: MON-88Ø17-3)≤ 0.0079%*
Bacillus thuringiensis Cry34Ab1 protein and the genetic material (vector PHP17662) necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7)  ≤ 0.0194%*
Bacillus thuringiensis Cry35Ab1 protein and the genetic material (vector PHP17662) necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7)≤ 0.0042%*
Other Ingredients:
CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) and the genetic material (vector PV-ZMIR39) necessary for its production in corn event MON 88017
PAT protein (phosphinothricin acetyl transferase) and the genetic material (vectors PHP17662 and PHP8999) necessary for its production in corn events TC1507 and DAS-59122-7≤ 0.00045%* *Maximum percent (wt/wt) of dry forage
‡ Genuity® SmartStax® RIB Complete™ seed with this refuge configuration contains 95% MON 89034 × TC1507 × MON 88017 × DAS-59122-7 mixed with at least 5% non-Bt corn within a single lot of seed.

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#### KEEP OUT OF REACH OF CHILDREN

#### CAUTION

NET CONTENTS\_

EPA Registration No. 524-595 EPA Establishment No. 524-MO-002

Monsanto Company 800 North Lindbergh Blvd. St. Louis, MO 63167

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#### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. This product must be used as specified in the terms and conditions of the registration.

This product may be combined or produced through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ protects corn crops from leaf, stalk, and ear damage caused by lepidopteran corn pests listed on this label and root damage caused by corn rootworm larvae listed on this label. In order to minimize the risk of these pests developing resistance to MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ corn, an insect resistance management plan must be implemented as defined in the registration terms and conditions.

Grower agreements will specify that growers must adhere to the refuge requirements that will be described on the bag or bag/tag for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>™</sup> corn or other applicable product use documents.

Sales of corn hybrids that contain Monsanto's Bt corn plant-incorporated pesticide(s) must be accompanied by either an IRM/Grower Guide or information on the bag or bag-tag, on planting, production, and insect resistance management, and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the Bt proteins is planted.

Corn seed bags or bag tags for products containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>™</sup> must include the refuge size requirement in text and graphical format.

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#### INSECT RESISTANCE MANAGEMENT

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Growers are instructed to read information on insect resistance management in the bag and/or bag-tag.

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per plant-incorporated protectant (PIP) active ingredient per registrant per year.

The seed producer must ensure a minimum of 5% non-PIP refuge seed is included with the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 in each lot of seed corn. The refuge seed in the seed mixture may not be treated with seed-applied insecticides for corn rootworm (CRW) control unless the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 seed in the seed mixture receives the same treatment.

The IRM/Grower Guide for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ or comparable information presented on the product bag or bag-tag, must contain the following information:

This product is a seed mixture containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 and a minimum of 5% non-Bt seed that when planted creates an interspersed refuge within the field. There are no requirements for a separate structured refuge for Genuity<sup>®</sup> SmartStax<sup>®</sup> RIB Complete<sup>TM</sup> corn when planted in the U.S. corn-growing region, including Alaska and Hawaii, because the refuge seed is contained within the bag/container.

The interspersed refuge can only be used by planting seed corn specifically generated by qualified seed producers/conditioners licensed by the registrant. Insecticidal treatments labeled for adult CRW control are discouraged during the time of adult CRW emergence.

The seed mix refuge option for Genuity<sup>®</sup> SmartStax<sup>®</sup> RIB Complete<sup>™</sup> satisfies the refuge requirements in all regions other than in the cotton-growing region where corn earworm is a significant pest as defined below.

# Additional refuge requirements in the cotton-growing region where corn earworm is a significant pest

In the cotton-growing region where corn earworm is a significant pest, as defined below, Genuity® SmartStax® RIB Complete™ requires the planting of an additional 20% structured refuge (i.e. 20 acres of non-Bt corn for every 80 acres of Genuity® SmartStax® RIB Complete™ planted).

The 20% refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn rootworms or corn borers. The refuge and the Genuity<sup>®</sup> SmartStax<sup>®</sup> RIB Complete<sup>™</sup> should be sown on the same day, or with the shortest window possible between

Monsanto Company 11-CR-192E-2R Page 98 of 110

planting dates to ensure that corn root development is similar among varieties. The structured refuge may be planted as an in-field or adjacent (e.g., across the road) refuge or planted as a separate block that is within ½ mile of the Genuity® SmartStax® RIB Complete™ field. In-field refuge options include blocks, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The refuge can be protected from lepidopteran damage by use of non-Bt insecticides if the population of one or more target lepidopteran pests of Genuity® SmartStax® RIB Complete™ in the refuge exceeds economic thresholds. In addition, the refuge can be protected from CRW damage by an appropriate seed treatment or soil insecticide; however, insecticides labeled for adult CRW control must be avoided in the refuge during the period of CRW adult emergence. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants).

The cotton-growing region requiring the additional 20% refuge consists of the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).

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#### Corn Insects Controlled or Suppressed

European corn borer (ECB)
Southwestern corn borer (SWCB)
Southern cornstalk borer (SCSB)
Corn earworm (CEW)
Fall armyworm (FAW)
Stalk borer
Lesser corn stalk borer
Sugarcane borer (SCB)
Western bean cutworm (WBC)
Black cutworm

Western corn rootworm (WCRW) Northern corn rootworm (NCRW) Mexican corn rootworm (MCRW) Ostrinia nubilalis
Diatraea grandiosella
Diatraea crambidoides
Helicoverpa zea
Spodoptera frugiperda
Papaipema nebris
Elasmopalpus lignosellus
Diatraea saccharalis
Richia albicosta
Agrotis ipsilon

Diabrotica virgifera virgifera Diabrotica barberi Diabrotica virgifera zeae

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 is a product of Monsanto's and Dow AgroSciences' research programs, offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents: 5322938, 5352605, 5359142, 5378619, 5424412, 5550318, 5554798, 5641876, 5717084, 5728925, 5804425, 6018100, 6025545, 6051753, 6063597, 6083878, 6331665, 6489542, 6645497, 6713063, 6962705, 7064249, 7070982, 7112665, 7227056, 7250501, 7304206, 7544862, 7618942, 7927598, and RE39247.

EPA Accepted: \_\_/\_/\_

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#### Plant-Incorporated Protectant Label

# MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>TM</sup> Insect-Protected, Herbicide-Tolerant Corn

Insect-Protected, Herbicide-Tolerant Corn
(Alternate Brand Name: Genuity® SmartStax® RIB Complete™)‡
(OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-1 ×
MON-88Ø17-3 × DAS-59122-7)

Active Ingredients:  Bacillus thuringiensis Cry1A.105 protein and the genetic material (vector PV-ZMIR245) necessary for its production in corn event MON 89034 (OECD Unique Identifier: MON-89Ø34-3)
≤0.0026%*
Bacillus thuringiensis Cry2Ab2 protein and the genetic material (vector PV-ZMIR245) necessary for its production in corn event MON 89034 (OECD Unique Identifier: MON-89034-3)≤ 0.0053%*
Bacillus thuringiensis Cry1F protein and the genetic material (vector PHP8999) necessary for its production in corn event TC1507 (OECD Unique Identifier: DAS-Ø15Ø7-I) ≤ 0.0012%*
Bacillus thuringiensis Cry3Bb1 protein and the genetic material (vector PV-ZMIR39) necessary for its production in corn event MON 88017 (OECD Unique Identifier: MON-88Ø17-3)≤ 0.0079%*
Bacillus thuringiensis Cry34Ab1 protein and the genetic material (vector PHP17662) necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7)≤ 0.0194%*
Bacillus thuringiensis Cry35Ab1 protein and the genetic material (vector PHP17662) necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7)
Other Ingredients:  CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) and the genetic material (vector PV-ZM1R39) necessary for its production in corn event MON 88017 ≤ 0.0052%*
PAT protein (phosphinothricin acetyl transferase) and the genetic material (vectors PHP17662 and PHP8999) necessary for its production in corn events TC1507 and DAS-59122-7≤0.00045%* *Maximum percent (wt/wt) of dry forage
and a second se
‡ Genuity® SmartStax® RIB Complete™ seed with this refuge configuration contains 95% MON 89034 × TC1507 × MON 88017 × DAS-59122-7 mixed with at least 5% non-Bt corn within a single lot of seed.

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#### KEEP OUT OF REACH OF CHILDREN

### **CAUTION**

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EPA Registration No. 524-595 EPA Establishment No. 524-MO-002

Monsanto Company 800 North Lindbergh Blvd. St. Louis, MO 63167

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#### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. This product must be used as specified in the terms and conditions of the registration.

This product may be combined or produced through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

MON 89034 × TC1507 × MON 88017 ×:DAS-59122-7 RIB Complete™ protects corn crops from leaf, stalk, and ear damage caused by lepidopteran corn pests listed on this label and root damage caused by corn rootworm larvae listed on this label. In order to minimize the risk of these pests developing resistance to MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ corn, an insect resistance management plan must be implemented as defined in the registration terms and conditions.

Grower agreements will specify that growers must adhere to the refuge requirements that will be described on the bag or bag/tag for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>™</sup> corn or other applicable product use documents.

Sales of corn hybrids that contain Monsanto's Bt corn plant-incorporated pesticide(s) must be accompanied by either an 1RM/Grower Guide or information on the bag or bag-tag, on planting, production, and insect resistance management, and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the Bt proteins is planted.

Corn seed bags or bag tags for products containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ must include the refuge size requirement in text and graphical format.

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#### INSECT RESISTANCE MANAGEMENT

Growers are instructed to read information on insect resistance management in the bag and/or bag-tag.

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per plant-incorporated protectant (PIP) active ingredient per registrant per year.

The seed producer must ensure a minimum of 5% non-PIP refuge seed is included with the MON  $89034 \times TC1507 \times MON 88017 \times DAS-59122-7$  in each lot of seed corn. The refuge seed in the seed mixture may not be treated with seed-applied insecticides for corn rootworm (CRW) control unless the MON  $89034 \times TC1507 \times MON 88017 \times DAS-59122-7$  seed in the seed mixture receives the same treatment.

The IRM/Grower Guide for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>™</sup> or comparable information presented on the product bag or bag-tag, must contain the following information:

This product is a seed mixture containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 and a minimum of 5% non-Bt seed that when planted creates an interspersed refuge within the field. There are no requirements for a separate structured refuge for Genuity<sup>®</sup> SmartStax<sup>®</sup> RIB Complete<sup>TM</sup> corn when planted in the U.S. corn-growing region, including Alaska and Hawaii, because the refuge seed is contained within the bag/container.

The interspersed refuge can only be used by planting seed corn specifically generated by qualified seed producers/conditioners licensed by the registrant. Insecticidal treatments labeled for adult CRW control are discouraged during the time of adult CRW emergence.

The seed mix refuge option for Genuity<sup>®</sup> SmartStax<sup>®</sup> RIB Complete<sup>™</sup> satisfies the refuge requirements in all regions other than in the cotton-growing region where corn earworm is a significant pest as defined below.

### Additional refuge requirements in the cotton-growing region where corn earworm is a significant pest

In the cotton-growing region where corn earworm is a significant pest, as defined below, Genuity<sup>®</sup> SmartStax<sup>®</sup> RIB Complete<sup>™</sup> requires the planting of an additional 20% structured refuge (i.e. 20 acres of non-Bt corn for every 80 acres of Genuity<sup>®</sup> SmartStax<sup>®</sup> RIB Complete<sup>™</sup> planted).

The 20% refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn rootworms or corn borers. The refuge and the Genuity<sup>®</sup> SmartStax<sup>®</sup> RIB Complete<sup>™</sup> should be sown on the same day, or with the shortest window possible between

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planting dates to ensure that corn root development is similar among varieties. The structured refuge may be planted as an in-field or adjacent (e.g., across the road) refuge or planted as a separate block that is within ½ mile of the Genuity® SmartStax® RIB Complete™ field. In-field refuge options include blocks, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The refuge can be protected from lepidopteran damage by use of non-Bt insecticides if the population of one or more target lepidopteran pests of Genuity® SmartStax® RIB Complete™ in the refuge exceeds economic thresholds. In addition, the refuge can be protected from CRW damage by an appropriate seed treatment or soil insecticide; however, insecticides labeled for adult CRW control must be avoided in the refuge during the period of CRW adult emergence. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants).

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The cotton-growing region requiring the additional 20% refuge consists of the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).

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### Corn Insects Controlled or Suppressed

European corn borer (ECB)
Southwestern corn borer (SWCB)
Southern cornstalk borer (SCSB)
Corn earworm (CEW)
Fall armyworm (FAW)
Stalk borer
Lesser corn stalk borer
Sugarcane borer (SCB)
Western bean cutworm (WBC)
Black cutworm

Western corn rootworm (WCRW) Northern corn rootworm (NCRW) Mexican corn rootworm (MCRW) Ostrinia nubilalis
Diatraea grandiosella
Diatraea crambidoides
Helicoverpa zea
Spodoptera frugiperda
Papaipema nebris
Elasmopalpus lignosellus
Diatraea saccharalis
Richia albicosta
Agrotis ipsilon

Diabrotica virgifera virgifera Diabrotica barberi Diabrotica virgifera zeae

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 is a product of Monsanto's and Dow AgroSciences' research programs, offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents: 5322938, 5352605, 5359142, 5378619, 5424412, 5550318, 5554798, 5641876, 5717084, 5728925, 5804425, 6018100, 6025545, 6051753, 6063597, 6083878, 6331665, 6489542, 6645497, 6713063, 6962705, 7064249, 7070982, 7112665, 7227056, 7250501, 7304206, 7544862, 7618942, 7927598, and RE39247.

EPA Accepted: \_/\_/\_

### Plant-Incorporated Protectant Label

### MON 89034 × TC1507 × MON 88017 × DAS-59122-7

RIB Complete<sup>TM</sup>
Insect-Protected, Herbicide-Tolerant Corn
(Alternate Brand Name: Genuity® SmartStax® RIB Complete<sup>TM</sup>)‡
(OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-I × MON-88Ø17-3 × DAS-59122-7)

MON-0-0717-3 ^ DAG-35122-7)
Active Ingredients:  Bacillus thuringiensis Cry1A.105 protein and the genetic material (vector PV-ZMIR245)  necessary for its production in corn event MON 89034 (OECD Unique Identifier: MON-89Ø34-3)  ≤ 0.0026%*
Bacillus thuringiensis Cry2Ab2 protein and the genetic material (vector PV-ZM1R245) necessary for its production in corn event MON 89034 (OECD Unique Identifier: MON-89Ø34-3) ≤ 0.0053%*
Bacillus thuringiensis Cry1F protein and the genetic material (vector PHP8999) necessary for its production in corn event TC1507 (OECD Unique Identifier: DAS- $\emptyset$ 15 $\emptyset$ 7-1) $\le 0.0012\%$ *
Bacillus thuringiensis Cry3Bb1 protein and the genetic material (vector PV-ZMIR39) necessary for its production in corn event MON 88017 (OECD Unique Identifier: MON-88Ø17-3) ≤ 0.0079%*
Bacillus thuringiensis Cry34Ah1 protein and the genetic material (vector PHP17662) necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7) ≤ 0.0194%*
Bacillus thuringiensis Cry35Ab1 protein and the genetic material (vector PHP17662) necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7) ≤ 0.0042%*
Other Ingredients: CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) and the genetic material (vector PV-ZMIR39) necessary for its production in corn event MON 88017≤ 0.0052%*
PAT protein (phosphinothricin acetyl transferase) and the genetic material (vectors PHP17662 and PHP8999) necessary for its production in corn events TC1507 and DAS-59122-7≤ 0.00045%* *Maximum percent (wt/wt) of dry forage
‡ Genuity® SmartStax® RIB Complete™ seed with this refuge configuration contains 95% MON 89034 × TC1507 × MON 88017 × DAS-59122-7 mixed with at least 5% non-Bt corn within a single lot of seed.

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### KEEP OUT OF REACH OF CHILDREN

### CAUTION

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NET CONTENTS

EPA Registration No. 524-595 EPA Establishment No. 524-MO-002

Monsanto Company 800 North Lindbergh Blvd. St. Louis, MO 63167

#### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. This product must be used as specified in the terms and conditions of the registration.

This product may be combined or produced through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>TM</sup> protects corn crops from leaf, stalk, and ear damage caused by lepidopteran corn pests listed on this label and root damage caused by corn rootworm larvae listed on this label. In order to minimize the risk of these pests developing resistance to MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>TM</sup> corn, an insect resistance management plan must be implemented as defined in the registration terms and conditions.

Grower agreements will specify that growers must adhere to the refuge requirements that will be described on the bag or bag/tag for MON 89034 × TC1507 × MON 88017 × DAS-59I22-7 RIB Complete<sup>™</sup> corn or other applicable product use documents.

Sales of corn hybrids that contain Monsanto's Bt corn plant-incorporated pesticide(s) must be accompanied by either an IRM/Grower Guide or information on the bag or bag-tag, on planting, production, and insect resistance management, and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the Bt proteins is planted.

Corn seed bags or bag tags for products containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>TM</sup> must include the refuge size requirement in text and graphical format.

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#### INSECT RESISTANCE MANAGEMENT

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Growers are instructed to read information on insect resistance management in the bag and/or bag-tag.

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per plant-incorporated protectant (PIP) active ingredient per registrant per year.

The seed producer must ensure a minimum of 5% non-PIP refuge seed is included with the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 in each lot of seed corn. The refuge seed in the seed mixture may not be treated with seed-applied insecticides for corn rootworm (CRW) control unless the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 seed in the seed mixture receives the same treatment.

The IRM/Grower Guide for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>TM</sup> or comparable information presented on the product bag or bag-tag, must contain the following information:

This product is a seed mixture containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 and a minimum of 5% non-Bt seed that when planted creates an interspersed refuge within the field. There are no requirements for a separate structured refuge for Genuity<sup>®</sup> SmartStax<sup>®</sup> RIB Complete<sup>TM</sup> corn when planted in the U.S. corn-growing region, including Alaska and Hawaii, because the refuge seed is contained within the bag/container.

The interspersed refuge can only be used by planting seed corn specifically generated by qualified seed producers/conditioners licensed by the registrant. Insecticidal treatments labeled for adult CRW control are discouraged during the time of adult CRW emergence.

The seed mix refuge option for Genuity<sup>®</sup> SmartStax<sup>®</sup> RIB Complete<sup>™</sup> satisfies the refuge requirements in all regions other than in the cotton-growing region where corn earworm is a significant pest as defined below.

### Additional refuge requirements in the cotton-growing region where corn earworm is a significant pest

In the cotton-growing region where corn earworm is a significant pest, as defined below, Genuity<sup>®</sup> SmartStax<sup>®</sup> RIB Complete<sup>™</sup> requires the planting of an additional 20% structured refuge (i.e. 20 acres of non-Bt corn for every 80 acres of Genuity<sup>®</sup> SmartStax<sup>®</sup> RIB Complete<sup>™</sup> planted).

The 20% refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn rootworms or corn borers. The refuge and the Genuity<sup>®</sup> SmartStax<sup>®</sup> RIB Complete<sup>TM</sup> should be sown on the same day, or with the shortest window possible between

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planting dates to ensure that corn root development is similar among varieties. The structured refuge may be planted as an in-field or adjacent (e.g., across the road) refuge or planted as a separate block that is within ½ mile of the Genuity® SmartStax® RIB Complete™ field. In-field refuge options include blocks, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The refuge can be protected from lepidopteran damage by use of non-Bt insecticides if the population of one or more target lepidopteran pests of Genuity® SmartStax® RIB Complete™ in the refuge exceeds economic thresholds. In addition, the refuge can be protected from CRW damage by an appropriate seed treatment or soil insecticide; however, insecticides labeled for adult CRW control must be avoided in the refuge during the period of CRW adult emergence. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants).

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The cotton-growing region requiring the additional 20% refuge consists of the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).

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### Corn Insects Controlled or Suppressed

European corn borer (ECB)
Southwestern corn borer (SWCB)
Southern cornstalk borer (SCSB)
Corn earworm (CEW)
Fall armyworm (FAW)
Stalk borer
Lesser corn stalk borer
Sugarcane borer (SCB)
Western bean cutworm (WBC)
Black cutworm

Western corn rootworm (WCRW) Northern corn rootworm (NCRW) Mexican corn rootworm (MCRW) Ostrinia nubilalis
Diatraea grandiosella
Diatraea crambidoides
Helicoverpa zea
Spodoptera frugiperda
Papaipema nebris
Elasmopalpus lignosellus
Diatraea saccharalis
Richia albicosta
Agrotis ipsilon

Diabrotica virgifera virgifera Diabrotica barberi Diabrotica virgifera zeae

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 is a product of Monsanto's and Dow AgroSciences' research programs, offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents: 5322938, 5352605, 5359142, 5378619, 5424412, 5550318, 5554798, 5641876, 5717084, 5728925, 5804425, 6018100, 6025545, 6051753, 6063597, 6083878, 6331665, 6489542, 6645497, 6713063, 6962705, 7064249, 7070982, 7112665, 7227056, 7250501, 7304206, 7544862, 7618942, 7927598, and RE39247.

EPA Accepted: \_\_/\_/\_

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# PROPERTIES. ATTACEMENT

Pages 237 247 - \* Claimed confidential by submitter\*



#### FOR IMMEDIATE RELEASE

MONSANTO U.S. MEGIA CONTACT

Ben Kampelman (314-694-6192)

Monsanto Completes U.S. Regulatory Registration for Genuity® SmartStax® RIB Complete™

Plans Set to Introduce Industry's First, Single-Bag Refuge Solution for Corn

ST. LOUIS (April XX, 2011) — U.S. farmers in the Corn Belt can now choose the simplicity, convenience and refuge compliance benefits of the industry's first, single-bag refuge solution for corn. Genuity® SmartStax® RIB Complete™ by Monsanto Company (NYSE: MON) has received registration from the U.S. Environmental Protection Agency. This completes federal regulatory authorization in the United States. Commercialization is pending individual state authorizations and notifications, as required.

The product is the outcome of a collaboration between Monsanto and Dow AgroSciences LLC, a wholly owned subsidiary of The Dow Chemical Company. It is a combination of each company's industry-leading corn traits that provide farmers with multiple modes-of-action for broad spectrum control of above- and below-ground insects, and also offers two herbicide tolerance traits for flexible weed management. Today's registration of Genuity SmartStax RIB Complete provides farmers with the opportunity to plant a single-bag refuge solution for corn.

Genuity SmartStax RIB Complete is a blend of 9S percent Genuity SmartStax corn seed and S percent refuge (non-Bt) seed that farmers can plant across their entire field. This means that farmers who plant Genuity SmartStax RIB Complete products no longer need to plant a separate, structured refuge for above- or below-ground pests in the Corn Belt. For farmers who have purchased Genuity SmartStax without the RIB Complete, the structured refuge is still required.

"We're committed to developing products that help improve farmers' productivity. Farmers have told us they want a true, single-bag refuge solution, and this registration enables Monsanto to deliver," said Brett Begemann, Monsanto Executive Vice President and Chief Commercial Officer. "For farmers planting a field of Genuity SmartStax RIB Complete corn, we've simplified refuge management by eliminating the structured refuge, which can contribute to timely, more efficient planting and on-farm productivity."

2012 Full Commercial Launch Remains On-Track

With the registration now in-hand, Monsanto confirms that it expects a full commercial launch in more than 100 seed brands in 2012. The company also expects <u>Genuity SmartStax RIB Complete</u> will be available in demonstration quantities in 2011 through Monsanto's national and regional seed brands, as well as through a limited number of licensing partners, primarily in the northern Corn Belt.

"This is a product that will truly simplify the management of my operation and improve my peace-ofmind at the same time," said Greene, Iowa, farmer Ron Litterer. "In order to be refuge compliant on my Genuity SmartStax RIB Complete fields, all I'll have to do is tear open the bag and pour the seed into my planter. That will allow me to plant the most traited acres in every field, while complying with refuge requirements."

In corn farming, a refuge is an integral component of insect resistance management. The refuge provides a shelter for insects susceptible to *Bt* technology so that any rare individual insects that survive after feeding on *Bt* corn can mate with susceptible insects and produce susceptible offspring. This preserves *Bt* technology that helps corn plants protect themselves from insect pests.

For downloadable audio, photographs and more, please visit the press kit on Monsanto's website.

#### About Monsanto

Monsanto Company is a leading global provider of technology-based solutions and agricultural products that improve farm productivity and food quality. Monsanto remains focused on enabling both small-holder and large-scale farmers to produce more from their land while conserving more of our world's natural resources such as water and energy. To learn more about our business and our commitments, please visit: <a href="www.monsanto.com">www.monsanto.com</a>. Follow our business on Twitter® at <a href="www.twitter.com/MonsantoCo">www.twitter.com/MonsantoCo</a>, on Facebook® at <a href="www.facebook.com/MonsantoCo">www.facebook.com/MonsantoCo</a>, or subscribe to our News Release RSS Feed.

Editors note: Monsanto corn seed brands and licensees in the Northern Corn Belt that are expected to have Genuity SmartStax RIB Complete product commercially available in 2011 include national brands DEKALB and Channel; regional brands Fontanelle, Gold Country Seed, Heritage, Hubner Seed, Jung, Kruger, Lewis, Reo, Specialty, Stewart, Stone Seed Graup and Trelay Seeds; and also licensees of Monsanto's seed technology.



### U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs Biopesticides and Pollution Prevention Division (7511P) Ariel Rios Building 1200 Pennsylvania Ave., NW Washington, D.C. 20460

EPA Reg. Number:

Date of Issuance:

524-595

APR 08 2011

Term of Issuance: Conditional

Name of Pesticide Product:

MON 89034 x TC1507 x MON 88017 x DAS-59122-7 RIB Complete Insect Protected. Herbicide-Tolerant Corn

NOTICE OF PESTICIDE:

x Registration \_ Reregistration (under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Monsanto Company 800 N. Lindbergh Blvd. St. Louis, MO 63167

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect bealth and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA § 3(c)(7)(A) provided that you do the following terms and conditions

- 1) Submit/cite all data required for registration of your product under FIFRA § 3(c)(5) when the Agency requires registrants of similar products to submit such data.
- 2) The subject registration will automatically expire on midnight October 31, 2011.
- 3) The subject registration is limited to MON 89034 x TC1507 x MON 88017 x DAS-59122-7 seed blend in field com.
- 4) Submit or cite all data required to support MON 89034 x TC1507 x MON 88017 x DAS-59122-7 plant-incorporated protectant products within the timeframes required by the terms and conditions of EPA Registration Numbers 524-581.

Signature of Approving Official:

08/82/2011

EPA Form 8570-6

- 5) Provided the registration expiration date is extended, submit an interim report on the following data within one year and a final report within two years.
  - Revised modeling incorporating the structural elements recommended by the SAP (i.e., explicit larval movement, switch from a frequency-based model to one including density-dependent larval mortality, epistatic mechanisms for resistance in target pests) with separate analyses for SWCB and ECB. Non-uniform oviposition should be modeled for both ECB and SWCB, especially (but not only) for the second generation of adults which will more likely lay eggs on Bt rather than on damaged (or crowded out) non-Bt refuge plants in seed blends.
  - Biological research on adult movement (related to mating and movement from refuges), larval movement, larval feeding (i.e., selective feeding within corn ears or on pollen), survival of heterozygote genotypes on MON 89034 x TC1507 x MON 88017 x DAS-59122-7 (markers may need to be determined for heterozygotes), and the potential for epistatic mechanisms of resistance (particularly with older instars).
- 6) Do the following Insect Resistance Management Program for MON 89034 x TC1507 x MON 88017 x DAS-59122-7 seed blend com.
- a) Refuge Requirements for MON 89034 x TC1507 x MON 88017 x DAS-59122-7

The following information must be included on the product bag or bag-tag as sold per respective region:

### Bag or Bag-Tag for the Corn-Growing Region

There are no requirements for a separate structured refuge for MON 89034 x TC1507 x MON 88017 x DAS-59122-7 seed blend corn when planted in the U.S. corn-growing region. The refuge seed of MON 89034 x TC1507 x MON 88017 x DAS-59122-7 seed blend corn is contained in the bag resulting in a refuge configuration that is interspersed within the field. SEE THE IRM/GROWER GUIDE FOR DETAILED IRM REQUIREMENTS, including the areas making up the corn-growing region.

#### Bag or Bag-Tag for the Cotton-Growing Region

Growers in the cotton-growing region of the U.S. who plant MON 89034 x TC1507 x MON 88017 x DAS-59122-7 seed blend corn are required to plant an additional 20% structured refuge (i.e. 20 acres of non-B.t. corn for every 80 acres of MON 89034 x TC1507 x MON 88017 x DAS-59122-7 seed blend corn planted). The 20% refuge must be planted with corn hybrids that do not contain B.t. technologies for the control of corn rootworms or corn borers. The refuge and the MON 89034 x TC1507 x MON 88017 x DAS-59122-7 seed blend corn should be sown on the same day, or with the shortest window possible between planting dates to ensure that corn root development is similar among varieties. The structured refuge may be planted as an in-field or adjacent (e.g., across the road) refuge, or as a separate block that is within ½ mile of the MON 89034 x TC1507 x MON 88017 x DAS-59122-7 seed blend corn field. SEE THE IRM/GROWER GUIDE FOR DETAILED IRM REQUIREMENTS, including the areas making up the cotton-growing region.

The cotton-growing region requiring the additional 20% refuge consists of the following states:

Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).

The following information regarding refuge placement for commercial production must be included in the IRM/Grower Guide:

This product includes refuge that is interspersed within the field by planting a licensed seed-mixture containing MON  $89034 \times TC1507 \times MON 88017 \times DAS-59122-7$  and a minimum of 5% non-PIP seed. The seed mix refuge option for MON  $89034 \times TC1507 \times MON 88017 \times DAS-59122-7$  seed blend corn satisfies the refuge requirements in all regions other than in cotton growing regions where corn earworm is a significant pest as defined below.

The seed producer must ensure a minimum of 5% non-PIP refuge seed is included with the MON  $89034 \times TC1507 \times MON 88017 \times DAS-59122-7$  in each lot of seed corn.

The interspersed refuge can only be used by planting seed corn specifically generated by qualified seed producers/conditioners licensed by the registrant. The refuge seed in the seed mixture may not be treated with seed-applied insecticides for corn rootworm (CRW) control unless the MON  $89034 \times TC1507 \times MON$   $88017 \times DAS-59122-7$  seed in the seed mixture receives the same treatment. Insecticidal treatments labeled for adult CRW control are discouraged during the time of adult CRW emergence.

### Additional refuge requirements in cotton-growing regions where corn earworm is a significant pest

In cotton-growing regions where corn earworm is a significant pest, as defined below, MON  $89034 \times TC1507 \times MON~88017 \times DAS-59122-7$  seed blend corn requires the planting of an additional 20% structured refuge (i.e. 20 acres of non-Bt corn for every 80 acres of MON 89034  $\times$  TC1507  $\times$  MON·88017  $\times$  DAS-59122-7 seed blend corn planted).

The 20% refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn rootworms or corn borers. The refuge and the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 seed blend corn should be sown on the same day, or with the shortest window possible between planting dates to ensure that corn root development is similar among varieties. The structured refuge may be planted as an in-field or adjacent (e.g., across the road) refuge, or as a separate block that is within ½ mile of the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 seed blend corn field. In-field refuge options include blocks, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The refuge can be protected from lepidopteran damage by use of non-Bt insecticides if the population of one or more target lepidopteran pests of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 seed blend corn in the refuge exceeds

economic thresholds. In addition, the refuge can be protected from CRW damage by an appropriate seed treatment or soil insecticide; however, insecticides labeled for adult CRW control must be avoided in the refuge during the period of CRW adult emergence. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants).

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The cotton-growing region requiring the additional 20% refuge consists of the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).

### b) Grower Agreement for MON 89034 x TC1507 x MON 88017 x DAS-59122-7 Seed Blend Corn

- 1) Persons purchasing MON 89034 x TC1507 x MON 88017 x DAS-59122-7 seed blend corn must sign a grower agreement. The term "grower agreement" refers to any grower purchase contract, license agreement, or similar legal document.
- 2) The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.
- 3) Monsanto must implement a system (equivalent to what is already approved for previously registered Monsanto Bt corn products), which is reasonably likely to assure that persons purchasing MON 89034 x TC1507 x MON 88017 x DAS-59122-7 seed blend corn will affirm annually that they are contractually bound to comply with the requirements of the IRM program. A description of the system must be submitted to EPA within 90 days from the date of registration.
- 4) Monsanto must use a grower agreement and must submit to EPA, within 90 days from the date of registration, a copy of that agreement and any specific stewardship documents referenced in the grower agreement. If Monsanto wishes to change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, 30 days prior to implementing a proposed change, Monsanto must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of this registration.
- 5) Monsanto must implement a system (equivalent to what is already approved for previously registered Monsanto Bt corn products), which is reasonably likely to assure that persons purchasing MON 89034 x TC1507 x MON 88017 x DAS-59122-7 seed blend corn sign grower

agreement(s). A description of the system must be submitted to EPA within 90 days from the date of registration.

- 6) Monsanto shall maintain records of all MON 89034 x TC1507x MON 88017 x DAS-59122-7 seed blend corn grower agreements for a period of three years from December 31st of the year in which the agreement was signed.
- 7) Beginning on January 31, 2012 and annually thereafter, Monsanto shall provide EPA with a report on the number of units of MON 89034 x TC1507 x MON 88017 x DAS-59122-7 seed blend corn seed shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of a twelve-month period. Note: The first report shall contain the specified information from the time frame starting with the date of registration and extending through the 2011 growing season.
- 8) Monsanto must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license number, will be protected.

### c) IRM Education and IRM Compliance Monitoring Program for MON 89034 x TC1507 x MON 88017 x DAS-59122-7 Seed Blend Corn

- 1) Monsanto must design and implement a comprehensive, ongoing IRM education program designed to convey to MON 89034 x TC1507 x MON 88017 x DAS-59122-7 seed blend corn users the importance of complying with the IRM program. The education program shall involve the use of multiple media, e.g. face-to-face meetings, mailing written materials, EPA-reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by internet, radio, or television commercials. Copies of the materials will be provided to EPA for their records. The program shall involve at least one written communication annually to each MON 89034 x TC1507 x MON 88017 x DAS-59122-7 seed blend corn user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. Monsanto shall coordinate its education program with the educational efforts of other registrants and other organizations, such as the National Corn Growers Association and state extension programs.
- 2) Annually, Monsanto shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.
- 3) Beginning January 31, 2012, Monsanto must provide a report to EPA summarizing the activities it carried out under its education program for the prior year. Annually thereafter, Monsanto must provide EPA any substantive changes to its grower education activities as part of the overall IRM compliance assurance program report. Monsanto must either submit a separate report or contribute to the report from the industry working group, Agricultural Biotechnology Stewardship Technical Committee (ABSTC).
- 4) Given that MON 89034 x TC1507 x MON 88017 x DAS-59122-7 seed blend will likely have different refuge strategies for lepidoptera and CRW than other registered Bt corn products,

Monsanto must submit a revised compliance assurance program (CAP) within 90 days of the date of registration. This revised CAP must be found acceptable by BPPD by April 1, 2012. This strategy should be specific for MON 89034 x TC1507 x MON 88017 x DAS-59122-7 seed blend corn and the new refuge requirements. Availability of non-Bt corn refuge seeds in desirable varieties must be addressed. Compliance is an area of ongoing concern -- recent data have shown that refuge compliance for Bt com has fallen in recent years.

### d) Insect Resistance Monitoring and Remedial Action Plans for MON 89034 x TC1507 x MON 88017 x DAS-59122-7 Corn

Existing programs for resistance monitoring and remedial action for MON 89034 x TC1507 x MON 88017 x DAS-59122-7 are applicable and required for MON 89034 x TC1507 x MON 88017 x DAS-59122-7 seed blend corn. Monsanto must submit a revised definition of unexpected damage in MON 89034 x TC1507 x MON 88017 x DAS-59122-7 seed blend corn for resistance monitoring must also submit a remedial action plan within 90 days of the date of registration that must be found acceptable to BPPD by April 1, 2012.

A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by August 31<sup>st</sup> each year, beginning in 2012, for the duration of the conditional registration.

### e) Annual Reporting Requirements for MON 89034 x TC1507 x MON 88017 x DAS-59122-7 Seed Blend Corn

- 1) Annual Sales: reported and summed by state (county level data available by request) January 31st each year, beginning in 2012;
- 2) Grower Agreements: number of units of MON 89034 x TC1507 x MON 88017 x DAS-59122-7 seed blend corn seed shipped or sold and not returned, and the number of such units that were soldto persons who have signed grower agreements, January 31st each year, beginning in 2011;
- 3) Grower Education: substantive changes to education program completed previous year, January 31st each year, beginning in 2012;
- 4) Compliance Assurance Program: compliance assurance program activities and results for the prior year and plans for the compliance assurance program for the current year, January 31st each year, beginning in 2012;
- 5) Compliance Survey Results: results of annual surveys for the prior year and survey plans for the current year; full report January 31st each year, beginning in 2012;
- 6) Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, August 31st each year, beginning in 2012.

### f) Refuge Assurance Program for MON 89034 x TC1507 x MON 88017 x DAS-59122-7 Seed Blend Corn

Monsanto and Monsanto's seed company licensees must continue to implement a blended seed refuge assurance program designed to ensure MON 89034 x TC1507 x MON 88017 x DAS-

59122-7 seed blend corn products are formulated with the appropriate rate of refuge seeds. The program must include the following four elements:

- 1. Trait purity check on seed lots prior to blending (Monsanto and Monsanto Licensees)
- 2. Standard Operating Procedures for the blending process;
- 3. Calibration of blending equipment; and
- 4. Records and data retention records for seed blend products.
  - Calibration records Monsanto and Monsanto's Licensees will retain documentation for three (3) years on the equipment calibration including the procedure, when it was conducted and the results.
  - Blend proportion records (weight and kernel based) Monsanto and Monsanto
    Licensees will retain documentation for three (3) years on the kernel per pound
    data of the components, the calculations to determine the proportions based on
    weight and the actual weights that are blended together to make up an MON
    89034 x TC1507 x MON 88017 x DAS-59122-7 seed blend corn product by seed
    lot.

All records must be maintained at the Monsanto and Monsanto Licensees blending facility and must be available for the EPA review upon request.

Within one year of the date of registration Monsanto will collect documentation from qualification test runs that validate blend percentages from their licensees/conditioners that produce MON 89034 x TC1507 x MON 88017 x DAS-59122-7 seed blend corn and submit this data to the Agency. Any licensee/conditioner that is unable to verify their blend accuracy will provide evidence demonstrating application and participation in the USDA USA Accredited Seed Conditioning Program (ASCP) as outlined in ARC 1005D Appendix, <a href="http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateN&navID=AccreditedSeedPrograms&rightNav1=AccreditedSeedPrograms&topNav=&leftNav=&page=ASLProgram&resultType=&acct=audrevcom.">http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateN&navID=AccreditedSeedPrograms&topNav=&leftNav=&page=ASLProgram&resultType=&acct=audrevcom.</a>

Should Monsanto or Monsanto's Licensees be notified by the USDA/AMS or State Seed Control Officials that your seed blend products have been found to have a lower percentage of the refuge component than is represented on the label, they must notify EPA within 30 days. This would constitute information reportable under FIFRA section 6(a)(2).

6) Monsanto must submit revised product labeling that indicates one seed tag for use in both cotton and non-cotton growing areas within six months.

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7) Monsanto must report on how many of their licensees (by number and percentage) color seed January 31st each year, beginning in 2012.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA Section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A copy of the stamped label is enclosed for your records.

Sincerely,

Keith A. Matthews, Director

Biopesticides and Pollution

Prevention Division (7511P)

### Plant-Incorporated Proteetant Label

### MON 89034 × TC1507 × MON 88017 × DAS-59122-7

### RIB Complete<sup>TM</sup>

Insect-Protected, Herbicide-Tolerant Corn
(Alternate Brand Name: Genuity<sup>®</sup> SmartStax<sup>®</sup> RIB Complete<sup>™</sup>)‡
(OECD Unique Identifier: MON-89Ø34-3 × DAS- Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7)

Active Ingredients:  Bacillus thuringiensis Cry1A.105 protein and the genetic material (vector PV-ZM1R245)  necessary for its production in corn event MON 89034 (OECD Unique Identifier: MON-89Ø34-3)  ≤ 0.0026%*						
Bacillus thuringiensis Cry2Ab2 protein and the genetic material (vector PV-ZMIR245) necessary for its production in corn event MON 89034 (OECD Unique Identifier: MON-89Ø34-3)≤0.0053%*						
Bacillus thuringiensis Cry1F protein and the genetic material (vector PHP8999) necessary for its production in corn event TC1507 (OECD Unique Identifier: DAS- $01507-1$ ) $\leq 0.0012\%$ *						
Bacillus thuringiensis Cry3Bb1 protein and the genetic material (vector PV-ZMIR39) necessary for its production in corn event MON 88017 (OECD Unique Identifier: MON-88Ø17-3)≤ 0.0079%*						
Bacillus thuringiensis Cry34Ab1 protein and the genetic material (vector PHP17662) necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7)≤ 0.0194%*						
Bacillus thuringiensis Cry35Ab1 protein and the genetic material (vector PHP17662) necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7)≤ 0.0042%*						
Other Ingredients: CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) and the genetic material (vector PV-ZMIR39) necessary for its production in corn event MON 88017						
PAT protein (phosphinothricin acetyl transferase) and the genetic material (vectors PHP17662 and PHP8999) necessary for its production in corn events TC1507 and DAS-59122-7≤ 0.00045%* *Maximum percent (wt/wt) of dry forage						
‡ Genuity® SmartStax® RIB Complete™ seed with this refuge configuration contains 95% MON 89034 × TC1507 × MON 88017 × DAS-59122-7 mixed with at least 5% non-Bt corn within a single lot of seed.						
Monsanto Company  07-CR-192E-2  Under the Federal Innecticides, Fungicide, and Redenticide Act. Forgrended, for the Particide Forgrended, for the Particide Forgrended and						

#### KEEP OUT OF REACH OF CHILDREN

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### CAUTION

NET CONTENTS

EPA Registration No. 524-XXX 59)
EPA Establishment No. 524-MO-002

Monsanto Company 800 North Lindbergh Blvd. St. Louis, MO 63167

### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. This product must be used as specified in the terms and conditions of the registration.

This product may be combined or produced through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ protects corn crops from leaf, stalk, and ear damage caused by lepidopteran corn pests listed on this label and root damage caused by corn rootworm larvae listed on this label. In order to minimize the risk of these pests developing resistance to MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ corn, an insect resistance management plan must be implemented as defined in the registration terms and conditions.

Grower agreements will specify that growers must adhere to the refuge requirements that will be described in the IRM/Grower Guide for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>TM</sup> corn or other applicable product use documents.

Sales of corn hybrids that contain Monsanto's Bt corn plant-incorporated pesticide(s) must be accompanied by an IRM/Grower Guide which includes information on planting, production, and insect resistance management and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the Bt proteins is planted.

Corn seed bags or bag tags for products containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ must include the refuge size requirement in text and graphical format.

Monsanio Company

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#### INSECT RESISTANCE MANAGEMENT

Growers are instructed to read information on insect resistance management in the IRM/Grower Guide.

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per plant-incorporated protectant (PIP) active ingredient per registrant per year.

The following information must be included on the product bag or bag-tag as sold per respective region:

### Bag or Bag-Tag for the Corn-Growing Region

There are no requirements for a separate structured refuge for Genuity® SmartStax® RIB Complete™ corn when planted in the U.S. corn-growing region. The refuge seed of Genuity® SmartStax® RIB Complete™ corn is contained in the bag resulting in a refuge configuration that is interspersed within the field. SEE THE IRM/GROWER GUIDE FOR DETAILED IRM REQUIREMENTS, including the areas making up the corn-growing region.

### Bag or Bag-Tag for the Cotton-Growing Region

Growers in the cotton-growing region of the U.S. who plant Genuity® SmartStax® RIB Complete™ corn seed are required to plant an additional 20% structured refuge (i.e. 20 acres of non-B.t. corn for every 80 acres of Genuity® SmartStax® RIB Complete™ corn planted). The 20% refuge must be planted with corn hybrids that do not contain B.t. technologies for the control of corn rootworms or corn borers. The refuge and the Genuity® SmartStax® RIB Complete™ corn should be sown on the same day, or with the shortest window possible between planting dates to ensure that corn root development is similar among varieties. The structured refuge may be planted as an in-field or adjacent (e.g., across the road) refuge, or as a separate block that is within ½ mile of the Genuity® SmartStax® RIB Complete™ corn field. SEE THE IRM/GROWER GUIDE FOR DETAILED IRM REQUIREMENTS, including the areas making up the cotton-growing region.

The cotton-growing region requiring the additional 20% refuge consists of the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).

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The following information regarding refuge placement for commercial production must be included in the IRM/Grower Guide:

1

This product includes refuge that is interspersed within the field by planting a licensed seed-mixture containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 and a minimum of 5% non-PIP seed. The seed mix refuge option for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>TM</sup> satisfies the refuge requirements in all regions other than in cotton growing regions where corn earworm is a significant pest as defined below.

The seed producer must ensure a minimum of 5% non-PIP refuge seed is included with the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 in each lot of seed corn.

The interspersed refuge can only be used by planting seed corn specifically generated by qualified seed producers/conditioners licensed by the registrant. The refuge seed in the seed mixture may not be treated with seed-applied insecticides for corn rootworm (CRW) control unless the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 seed in the seed mixture receives the same treatment. Insecticidal treatments labeled for adult CRW control are discouraged during the time of adult CRW emergence.

### Additional refuge requirements in cotton-growing regions where corn earworm is a significant pest

In cotton-growing regions where corn earworm is a significant pest, as defined below, MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>™</sup> requires the planting of an additional 20% structured refuge (i.e. 20 acres of non-Bt corn for every 80 acres of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>™</sup> planted).

The 20% refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn rootworms or corn borers. The refuge and the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ should be sown on the same day, or with the shortest window possible between planting dates to ensure that corn root development is similar among varieties. The structured refuge may be planted as an in-field or adjacent (e.g., across the road) refuge, or as a separate block that is within ½ mile of the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ field. In-field refuge options include blocks, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The refuge can be protected from lepidopteran damage by use of non-Bt insecticides if the population of one or more target lepidopteran pests of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ in the refuge exceeds economic thresholds. In addition, the refuge can be protected from CRW damage by an appropriate seed treatment or soil insecticide; however, insecticides labeled for adult CRW control must be avoided in the refuge during the period of CRW adult emergence. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants).

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The cotton-growing region requiring the additional 20% refuge consists of the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).

### Corn Insects Controlled or Suppressed

European corn borer (ECB)
Southwestern corn borer (SWCB)
Southern cornstalk borer (SCSB)
Corn earworm (CEW)
Fall armyworm (FAW)
Stalk borer
Lesser corn stalk borer
Sugarcane borer (SCB)
Western bean cutworm (WBC)
Black cutworm

Western corn rootworm (WCRW)
Northern corn rootworm (NCRW)
Mexican corn rootworm (MCRW)

Ostrinia nubilalis
Diatraea grandiosella
Diatraea crambidoides
Helicoverpa zea
Spodoptera frugiperda
Papaipema nebris
Elasmopalpus lignosellus
Diatraea saccharalis
Richia albicosta
Agrotis ipsilon

)

Diabrotica virgifera virgifera Diabrotica barberi Diabrotica virgifera zeae

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete<sup>TM</sup> is a product of Monsanto's and Dow AgroSciences' research programs, offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents: 5322938, 5352605, 5359142, 5378619, 5424412, 5554798, 5641876, 5717084, 5728925, 5804425, 6018100, 6025545, 6051753, 6063597, 6083878, 6331665, 6489542, 6645497, 6962705, 7064249, 7227056, and 7250501.

EPA Accepted: \_\_/\_/\_

Monsanto Company

07-CR-192E-2

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## Public Participation for EPA-HQ-OPP-2011-0362 Pesticide Product; Registration Issuances for PIP Seed Blend Anthia Peters to: Mike Mendelsohn, Robert Forrest, Kimberly Smith, Earl Ingram

04/08/2011 04:10 PM

Cc: Latasha White

The documents for EPA-HQ-OPP-2011-0362 (BRAD) Pesticide Product; Registration Issuances for PIP Seed Blend are now available on Regulations.gov

Anthia C. Peters Office of Pesticides Programs Docket Manager ASRC Management Services (703) 305-0032

Monsanto

DRAFT

BPPD has reviewed the information provided regarding the manufacturing process in Monsanto owned facilities and concludes that:

The seed weighing technology should guarant high accuracy around the determined target (mean weight or mean percentage) with very low expected variance provided that all of Monsanto's manufacturing plants maintain and follow the same procedures;

\* The seed mixing technology will be set to satisfy growers expectation of uniformity but some degree of clumping of refuge seed may be possible. BPPD does not expect clumping of refuge plants in the field to impact IRM for ECB and SWCB (see BPPD 2011) because of very little expected asymmetrical movement between the two plant types (Bt and non-Bt) for both species as supported by Onstad and Gould (1998);

• Bt and refuge seed will be colored differently when seed blends are mixed in Monsanto owned manufacturing plants. Monsanto is also encouraging its seed company licensees to color the Bt and refuge seed differently. Coloring the two types of seed differently will provide an additional affirmation that the product is in fact a seed blend. It will also allow the applicant to more easily test for germination of refuge seed (to assure the 5% refuge is still guaranteed);

Monsanto has submitted additional information and a generic standard operating procedure to guarantee the same accuracy and quality assurance from independent seed dealers who are in charge of their own seed mixing process. Unfortunately, this information was very general and

SmartStax® B.t. Corn Seed Blend
Biopesticides Registration Action Document

Contains no CBI

Contains no CBI

Contains no CBI

Authorized to CBI

A 17/11

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### SmartStax RIB SCHNEIDER, RUSSELL P [AG/1920]

Mike Mendelsohn 04/08/2011 01:59 PM Show Details

Only submissions made to EPA in support of the SmartStax RIB petition which were PR Notice 86-5 compliant and/or contained data are considered as Confidential Business Information by Monsanto.

Dr. Russell P. Schneider Senior Director, Regulatory Affairs and Policy Monsanto Company 1300 I St., NW Suite 450 East Washington, DC 20005 202/383-2866

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<b>≎</b> EPA	<b>Environme</b> l Wa		Ar	gistration nendment her	OPP Identifier Number		
	Applica	ation for P	<u>esticide – S</u>	Section I	2000	2 2000	
Company/Product Number     File System	mbol 524-XXX		2. EPA Produc	t Manager Sheryl Rei	lly	3. Рюро	osed Classification
Company/Product (Name) MON 89034 × TCI 507 × MON	88017 × DAS-59122-7 R	IB Complete	PM# None Restricted				ne Restricted
5. Name and Address of Applicant (Include ZIP Code) Monsanto Company 800 North Lindbergh Blvd. St. Louis, MO 63167  Check if this is a new address			Expedited Review. In accordance with FtFRA Section 3(c)(3)(B)(i), my product is similar or identical in composition and labeling to:  EPA Reg. No.  Product Name				
		Sect	ion – II	1			
Amendment – Expt Resubmission in re Notification – Expta	sponse to Agency letter da	ated		Final printe Agency lett "Me Too" A Other – Exp	pplication.	ponse to	
Explanation: Use additional page(s) if necessary. (For Section I and Section II.)  Application to Register the Plant-Incorporated Protectant, Bocillus Illuringiensis Cryl A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1 and Cry35Ab1  Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 ×  TC1507 × MON 88017 × DAS-59122-7, with an interspersed in-field refuge configuration using a seed mixture.							
		Secti	on – III	2555.55			
1. Material This Product Will Be I Child-Resistant Packaging Yes* No * Certification must be submitted	Unit Packaging Yes No If "Yes" Unit Packaging wgt.	No. per Container	Water Sotuble P Yes No If "Yes" Package wgt.	ackaging No. per Container	2. Ty	De of Container    Metal   Plastic   Glass   Paper   Other	
3. Location of Net Contents Information  Label Container	ion	4. Size(s) Reta	Il Container Various		5. Location On Lat	of Label Direction	
6. Manner in Which Label is Affixed to Product    Lithograph   Other							
Section – IV  1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)							
Name Russell P. Schneider, Ph.D. Senior Regula Certification			Director, atory Affairs a	and Policy		Telephone No. Code)	(Include Area 383-2866 6. Date Application
t certify that the statements I have made on this form and all attachments thereto are true, accurate and complete.  I acknowledge that any knowingty false or misteading statement may be punishable by fine or imprisonment or both under applicable law.  Received  (Stamped)				Received (Stamped)			
2. Signature 3. Title			Regulatory	Affairs Ma	nager		german van Andrewske van de
4. Typed Name J. Austin Burns, Ph.D.	Tel. (314) 694-6	5. Date	April 6, 201	1		77774	

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete.

White - EPA File Copy (original) Yellow Applicant Copy



### UNIT ) STATES ENVIRONMENTAL PR/ ECTION AGENCY 401 M Street, S. W. WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data						
Applicant's/Registrant's Name, Address, and Telephone Number: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis,	EPA Registration Number / File Symbol:					
(314) 694-6514		524-XXX				
Active Ingredient(s) and/or representative test com		Date:				
Bacillus thuringiensis Cry1A. 105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1 and Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP1 Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7	d Cry35Ab1 Proteins and the 7662) Necessary for their	April 6, 2011				
General Use Pattern(s) (list all those claimed for this product using 40	CFR Part 158:	Product Name:				
Terrestrial field crop		MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete				
NOTE: If your product is a 100% repackaging of another purchase need to submit this form. You must submit the Formulator's Exemption						
! am responding to a Data-Call-in Notice, and have included v should be used for this purpose).	with this form a list of companie	s sent offers of compensation (the Data Matrix form				
Section I: METHOD OF DA	TA SUPPORT (Check	one method only)				
t am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix Form should be used for this purpose).  I am using the selective method of support (or cite-all op the selective method), and have included with this form completed list of data requirements (the Data Matrix form used).						
Section II: GE	NERAL OFFER TO PA	ΑY				
(Required if using the cite-all method or when using the cite-a	It option under the selective ma	ethod to satisfy one or more data requirements)				
I hereby offer and agree to pay compensation, to other person		of this application, to the extent required by FIFRA.				
The second secon	I: CERTIFICATION					
I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for registration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.						
I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.						
t certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.						
I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.						
I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowled ge that any knowingly false of misleading statement may be punishable by fine or imprisonment of both under the applicable law.						
Signature	Date	Typed or Printed Name and Title				
J.an	April 6, 2011	J. Austin Burns Regulatory Affairs Manager				

EPAForm 8570-34 (9-97) Electronic and Paper Versions available. Submit only Paper version.

Form Approved OMB No. 2070-0060



### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

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<u> </u>	DA	ATA MATRIX	200	N. J. Dreit		
Date: April 6, 2011				Reg. No./File Symbol: 524-XX	X Page Lof 57	
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167				Product: MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete		
	nsis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab Production in MON 89034 × TC1507 × MON 88017 ×					
Guideline Reference Number	Guideline Sludy Name	MRID Number	Submitter	Status	Note	
ŊA	Administrative Materials for the Application to Register the Plant-Incorporated Protectant, Bacillus thuringiensis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, With an Interspersed In-Field Refuge Configuration Using a Seed	a	Monsanto Company	OWN	Administrative This Application	
Ŋ <b>A</b>	Five Percent Seed Mix Refuge as an Insect Resistance Management Option for MON 89034 × TC1507 × MON 88017 × DAS-59122-7	***************************************	Monsanto Company	OWN	Supporting Data This Application	
NA	The Benefits of a 5% Interspersed In-field Refuge Option for SmartStax <sup>TM</sup> Corn		Monsanto Company	OWN	Benefits This Application	
Signature / CV			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Mana	Date April 6, 2011	**************************************	

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Agency Internal Use

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### **⊗**EPA

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		Washington, D.	C. 20460			
response for reregistration and other aspect of this collection o	tice: The public reporting burden for this collec special review activities, including time for read finformation, including suggestions for reducing n, DC 20460. Do not send the form to this addi	ding the instructions and completing the burden to: Director, OPPE Ir	g the necessary forms. Send	comments regarding the bure	len estimate or any	
	700	DATA MATRIX				
Date: April 6, 2011			EPA	Reg. No /File Symbol: 524-X	XX Page 2 of 57	
Applicant's/Registrant's Name & Address:  Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167				Product: MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete		
Ingredient Bacillus thuringie PHP17662) Necessary for thei 59122-7)	nsis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, r Production in MON 89034 × TC1507 × MO	Cry34/35Ab1 Proteins and the Go N 88017 × DAS-59122-7 (OECD	netic Materiols (Vectors PV- Unique Identificr: MON-89	ZMIR245, PHP8999, PV-Zi Ø34-3 × DAS- Ø15Ø7 × MC	MIR39, and N- 88Ø17-3× DAS-	
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note	
			Monsauto Company  Monsauto Company	OWN	Administrative Product Characterization	
		-	Monsanto Company	OWN	Product Characterization	
			Monsanto Company	OWN	Product Clustacterization	
Signature	ev		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date April 6, 2011		

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Revised GENSS RIB Complete EPA label - revision BURNS, J AUSTIN [AG/1000]

to:

Mike Mendelsohn 04/06/2011 06:08 PM

Cc:

"SCHNEIDER, RUSSELL P [AG/1920]" Show Details

#### 1 Attachment



Revised GENSS RIB Complete label 4-6-2011 v2.pdf

<< Revised GENSS RIB Complete label 4-6-2011 v2.pdf>>

Mr. Mendelsohn. I am attaching a second version of the revised GENSS RIB Complete label with more consistent product naming throughout the document. I apologize for any inconvenience. Please refer to this version 2, and ignore the earlier version in my email from 2:08 PM.

As mentioned in my previous note, Monsanto utilizes an IRM/Grower guide, in addition to the bag-tag, that growers refer to for IRM instructions and conditions. Language requirements for both the bag/bag-tag and the IRM/Grower Guide are addressed in this revised label. In particular, the details of refuge requirements per states/counties are addressed in the Grower Guide. Our preference is to maintain this format (the bag-tags provide basic information and refer to the greater details in the grower guide). This provides a consistent location for guidance to growers across our Bt products, and works within the inherent space limitations on the bag-tags. Some differences in communication tools exist between Bt corn technology providers who may not utilize Grower Guides, and thus would need to include all the specific state/county information using very small font on the bag-tags. Monsanto prefers flexibility in our approach as this provides the most clarity to growers.

I hope this proposed approach between the bag/tag and the IRM/Grower Guide will satisfy your needs, and we provide language for both documents (bag/bag-tags and the IRM/Grow Guide) in the attached draft label. If this proposal is still a concern, I hope this format will be possible for the projected 2011 season (bag tags already printed), and if more significant changes are needed to the bag-tag, those could be made for the 2012 season.

Regards,

Regards,

Austin Burns, Monsanto

314-694-6514

From: BURNS, J AUSTIN [AG/1000] Sent: Wednesday, April 06, 2011 2:08 PM

To: 'mendelsohn.mike@epa.gov'
Cc: SCHNEIDER, RUSSELL P [AG/1920]

Subject: Revised GENSS RIB Complete EPA label and Forms

Importance: High

Mr. Mendelsohn, please see the revised draft EPA label and application forms to reflect the changes you requested this morning. Please note, a portion of this label lists required language for the [Bag or Bag-Tag], and a second portion of the label refers to language to be included in the [IRM/Grower Guide]. Because the IRM/Grower Guide will contain many details for geographical IRM conditions, lists of states & county details, as well as a map and other graphical depictions, that document is the key piece information growers obtain such information. I hope this proposed approach between the bag/tag and the IRM/Grower Guide will satisfy your needs, and/or will be possible for the projected 2011 season (tags already printed), and more significant changes to the tag if necessary could be made for the 2012 season. Please don't hesitate to call if we should discuss further:

Regards,

Austin Burns, Monsanto

314-694-6514

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### & EPA

### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S. W. WASHINGTON, D.C. 20460

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Environmental Protection Agency, 401 M Street, S.W., Washington DC, 20460. Do not send the completed form to this address.						
Certification with Respect to Citation of Data						
Applicant's/Registrant's Name, Address, and Telephone Number: Monsanto Company, 800 N, Lindbergh Blvd., St. Louis, (314) 694-6514	EPA Registration Number / File Symbol: 524-XXX					
Active Ingredient(s) and/or representative test corr Bacillus rhuringlensis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1 an Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP1 Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7	Date: April 6, 2011					
General Use Pattem(s) (list all those claimed for this product using 40 Terrestrial field crop	Product Name: MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Comptets					
NOTE: if your product is a 100% repackaging of another purchased need to submit this form. You must submit the Formulator's Exemption		ied for all the same uses on your label, you do not				
i am responding to a Data-Cail-in Notice, and have included y should be used for this purpose).	vith this form a list of companie	es sent offers of compensation (the Data Matrix form				
Section I: METHOD OF DA	TA SUPPORT (Check	one method only)				
i am using the cite-all method of support, and have included very this form a list of companies sent offers of compensation (the Data Matrix Form should be used for this purpose).	e seiective method of support (or cile-ail oplion under method), and have included with this form a t of data requirements (the Data Mainx form must be					
Section II: GE	NERAL OFFER TO P	AY				
[Required if using the cite-ail method or when using the cite-a						
i hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FiFRA.  Section III: CERTIFICATION						
i certify that this application for registration, this form for reregistration, or this Data-Cali-in response is supported by all data submitted or cited in the application for registration, the form for registration, or the Data-Cali-in response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section t, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.						
i certify that for each exclusive use study cited in support of this registration or reregistration, that i am the original data submitter or that i have obtained the written permission of the original data submitter to cite that study.						
i certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either; (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.						
i certify that in ati instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FiFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformtly with FiFRA.						
i certify that the statements i have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false of misleading statement may be punishable by fine or imprisonment of both under the applicable law.						
Signature	Date	Typed or Printed Name and Title				
J.an	April 6, 2011	J. Austin Burns Regulatory Affairs Manager				

SPACForm 8570-34 (9-97) Electronic and Paper Versions available. Submit only Paper version.

Form Approved, OMB No. 2070-0060. Approval Expires 2-28-95

<b>⊕</b> EPA	United S <b>Environmental Pro</b> Washinglon,	otection Agen	cy 📙 Ar	gistration mendment ther	OPP Identifier Number
	Application fo	r Pesticide - S	Section I		
t. Company/Product Number File Syr	nbol 524-XXX	2. EPA Produc	ct Manager Sheryl Reilly	3, Propo	osed Classification
Company/Product (Name)	88017 × DAS-59122-7 RIB Compl	PM#	92	No.	one Restricted
5. Name and Address of Applicant of Monsanto Company 800 North Lindbergh Blvd. St. Louis, MO 63167  Check if this is a new address	Include ZIP Code)	6. Expedited product is simil EPA Reg. Not Product Name	d Review. In accordance lar or identical in compositio o.	on and labeling I	do:
	S	ection - II			
Amendment – Expla	sponse to Agency letter dated		Final printed labels in read Agency letter dated "Me Too" Application. Other – Explain below.	sponse to	
Application to Register the Plant-Ir Proteins and the Genetic Materials	e(s) if necessary. (For Section I and toorporated Protectant, Bacillus rhuid (Vectors PV-ZMtR245, PHP8999, 122-7, with an interspersed in-field	ringiensis Cryl A.105, PV-ZM1R39, and PHI refuge configuration u	(17662) Necessary for their	i, Cry34Abl ar r Production in	nd Cry35Ab1 MON 89034 ×
	The state of the s	ection – III			
t. Material This Product Will Be F Child-Resistant Packaging Yes* No * Certification must be submitted	Unit Packaging Yes No No No. per Unit Packaging wgt. Container	Waler Soluble F Yes No If "Yes" Package wgi.	No. per Container  2. Ty	pe of Container  Metai  Plastic  Glass  Paper  Other	
3. Location of Net Contents Information  Label Container	ion 4. Size(s)	Retail Container Various	On La	of Labe! Directi bei beling accompa	
6. Manner in Which tabel is Affixed i	Pap Sler	ograph er glued ndiled	Other Other		
L Control Colon (Consultate if consultate		ection - IV	fanconani la arragna late	annilanilan l	· · · · · · · · · · · · · · · · · · ·
t. Contact Point (Complete ilems dir Name	ectly below for identification of indivi		necessary, to process this	20 (00 (00 A) B	. (Include Area
Russell P. Schn	eider, Ph.D. Se	enior Director, egulatory Affairs a	and Policy	Code)	383-2866
	Certificative made on this form and elf attaching false or misfeading stetement ma	on ments thereto are true,	accurate and complete.	26 XM 8) 26 6	6. Date Application Received (Stamped)
2. Signature	3.	Title Regulatory	Affairs Manager		(wompou)
4. Cyped Name J. Austin Burns, Ph.D.	Tel. (314) 694-6514 5.	Date April 6, 20	11		

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete.

White - EPA File Copy (original) Yellow Applicant Copy

Monsanto Company

07-CR-192E-2

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Form Approved OMB No. 2070-0060

### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

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	ATA MATRIX				
Date: April 6, 2011					
Applicant's/Registrant's Name & Address:  Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167			Product: MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RJB Complete		
nsis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab Production in MON 89034 × TC1507 × MON 88017 × I	of Proteins and the DAS-59122-7 (OEC	Genetic Materials (Vectors PV- CD Unique Identifier: MON-89	ZMIR245, PHP8999, PV-Z Ø34-3 × DAS-Ø15Ø7-t × M	MIR39, and ION-88Øt7-3 ×	
Guideline Study Name	MRID Number	Submitter	Status	Note	
Administrative Materials for the Application to Register the Plant-Incorporated Protectant, Bacillus thuringtensis Cryl A. 105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507.× MON 88017 × DAS-59122-7, With an Interspersed In-Field Refuge Configuration Using a Seed Mixture	et e	Monsanto Company	OWN	Administrative This Application	
Five Percent Seed Mix Refuge as an Insect Resistance Management Option for MON 89034 × TC1507 × MON 88017 × DAS-59122-7		Monsanto Company	OWN	Supporting Data This Application	
The Benefits of a 5% Interspersed In-field Refuge Option for SmartStax™ Corn		Monsanto Company	OWN	Benefits This Application	
v	<del> </del>	Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manage	Date April 6, 2011		
	A Lindbergh Blvd., St. Louis, MO 63167  Insis Cryl A.105, Cry2Ab2, CrylF, Cry3Bb1, Cry34/35Al Production in MON 89034 × TC1507 × MON 88017 ×  Guideline Study Name  Administrative Materials for the Application to Register the Plant-Incorporated Protectant, Bacillus Ithuringtensis Cryl A.105, Cry2Ab2, CrytF, Cry3Bbt, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, With an Interspersed In-Field Refuge Configuration Using a Seed Mixture  Five Percent Seed Mix Refuge as an Insect Resistance Management Option for MON 89034 × TC1507 × MON 88017 × DAS-59122-7  The Benefits of a 5% Interspersed In-field Refuge Option for SmartStax <sup>TM</sup> Corn	Lindbergh Blvd., St. Louis, MQ 63167  Insis Cryl A.105, Cry2Ab2, CrylF, Cry3Bb1, Cry34/35Abt Proteins and the Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OEG Guideline Study Name MRID Number    Administrative Materials for the Application to Register the Plant-Incorporated Protectant, Bacillus thuringlensis Cryl A.105, Cry2Ab2, CrylF, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, With an Interspersed In-Field Refuge Configuration Using a Seed Mixture  Five Percent Seed Mix Refuge as an Insect Resistance Management Option for MON 89034 × TC1507 × MON 88017 × DAS-59122-7  The Benefits of a 5% Interspersed In-field Refuge Option for SmartStax <sup>TM</sup> Corn	Address: Lindbergh Blvd., St. Louis, MO 63167  Insis Cryl A.105, Cry2Ab2, CrylF, Cry3Bb1, Cry34/35Abt Proteins and the Genetic Materials (Vectors PV-Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identifier: MON-890  Guideline Study Name    MRID Number	Administrative Materials for the Application to Register the Plant-Incorporated Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-Z Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON 88017 × DAS	

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Washington, D.C. 20460

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		DATA MATRIX		55 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5	
Date: April 6, 2011			E	PA Reg. No./File Symbol: 524-X	XX Page 2 of 5
pplicanl's/Registranl's Name of Monsanto Company, 800 N	& Address: I. Lindbergh Blvd., St. Louis, MO 6316'	7	223	Produci: MON 89034 × TC150 DAS-59122-7 RIB C	
ngredient Bacillus thuringie PHP17662) Necessary for thei 19122-7	msis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bbl r Production in MON 89034 × TC1507 × M	I, Cry34/35Ab1 Proteins and the Ger ION 88017 × DAS-59122-7 (OECD	netic Materials (Vectors) Unique Identificr: MON	PV-ZMIR245, PHP8999, PV-ZN -89Ø34-3 × DAS- Ø15Ø7 × MO	MIR39, and N- 88Ø17-3× DAS
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Compan	y OWN	Administrative  Product Characterization
			Monsanto Compan		Product Characterizatio
			Monsanto Compan		Product Characterizatio
Signature	ev	13	Name and Title  I. Austin Burns, Ph.D.  Regulatory Affairs Mana	Date April 6, 2011	T-853 8 6 July 2

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

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Form Approved OMB No. 2070-0060



Revised GENSS RIB Complete EPA label and Forms BURNS, J AUSTIN [AG/1000]

Mike Mendelsohn 04/06/2011 03:08 PM

Cc:

"SCHNEIDER, RUSSELL P [AG/1920]" Show Details

2 Attachments





Revised GENSS RIB Complete EPA forms 4-6-2011.PDF Revised GENSS RIB Complete EPA label 4-6-2011.pdf

Mr. Mendelsohn, please see the revised draft EPA label and application forms to reflect the changes you requested this morning. Please note, a portion of this label lists required language for the [Bag or Bag-Tag[, and a second portion of the label refers to language to be included in the [IRM/Grower Guide]. Because the IRM/Grower Guide will contain many details for geographical IRM conditions, lists of states & county details, as well as a map and other graphical depictions, that document is the key piece information growers obtain such information. I hope this proposed approach between the bag/tag and the IRM/Grower Guide will satisfy your needs, and/or will be possible for the projected 2011 season (tags already printed), and more significant changes to the tag if necessary could be made for the 2012 season. Please don't hesitate to call if we should discuss further:

Regards, Austin Burns, Monsanto 314-694-6514

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## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

March 29, 2011

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

RUSSELL P. SCHNEIDER MONSANTO COMPANY MONSANTO COMPANY 1300 I STREET, NW, SUITE 450 EAST WASHINGTON, DC 20005-

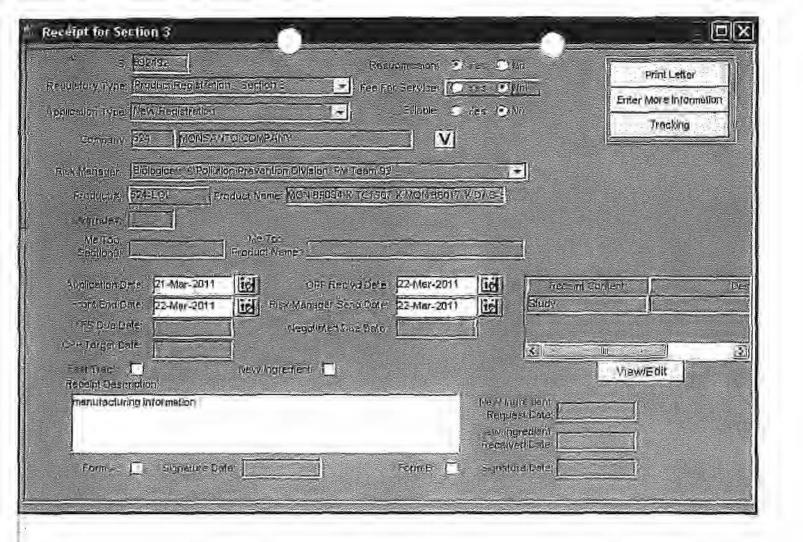
Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 22-MAR-11. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

We are unable to accept your data submittal for further processing and review, because of the significant deficiencies noted below. It is being returned to you for correction. If deficiencies were found which apply to your overall submission, they are described immediately following this paragraph. If problems are found with individual studes, they are described below linked to the study identifier found on the enclosed copy of your bibliography.

### Rejected Study [01]:

- \* Judging from the pagination of the study, pages <u>36-38</u> were omitted from the submitted copy.
- \* Your Statement of No Data Confidentiality Claims is contradicted by the markings on pages <u>1-35</u> of the study. If you do not intend to make Supplemental Claims of Data Confidentiality you can explicitly override these markings when you resubmit this study.





Monsanio Comeany 800 N. Lindbergh Blvo. St. Louis, Missouri 63:67 http://www.monsanto.com

March 21, 2011

Document Processing Desk Office of Pesticide Programs (7504P) U.S. Environmental Protection Agency Room S-4900, One Potomac Yard 2777 South Crystal Drive Arlington, VA 22202-4501

Attn:

Dr. Sheryl Reilly, Branch Chief, Microbial Pesticides Branch, Biopesticide and

Pollution Prevention Division (7511P)

Subject:

Monsanto and Monsanto Licensee SmartStax® RIB Manufacturing Standard

Operating Procedures; EPA File Symbol 524-LOL

### Dear Dr. Reilly:

Pursuant to the SmartStax® RIB registration request currently pending with the Agency, Monsanto hereby submits manufacturing information pertinent to both Monsanto (DeKalb) and a Monsanto licensee (Wyffels). Accompanying this letter are four manufacturing Standard Operating Procedures (SOPs) for your review. These SOPs describe the blending process for a seed mix of 95% SmartStax (MON 89034 × TC1507 × MON 88017 × DAS-59122-7) with 5% non-Bt seed.

The documents accompanying this letter have been classified "A" or "B", as defined by the Agency:

- Category "A": Materials that can be released to anyone, regardless of affiliation to a foreign or multi-national pesticide producer.
- Category "B": Information can be released only to individuals that attest they are not employees or agents of a foreign or multi-national pesticide producer, as per FIFRA Section 10(g).

Documents accompanying this letter:

Document	Category
Cover letter	A
Transmittal document	Α
Administrative Materials for Monsanto and Monsanto Licensee SmartStax® RIB Manufacturing Standard Operating Procedures	A
Monsanto and Monsanto Licensee SmartStax® RIB Manufacturing Standard Operating Procedures	В

If you have any questions regarding this submission, please do not hesitate to contact Dr. Russell P. Schneider at 202-383-2866 or myself at 314-694-6425.

Sincerely,

Jeffrey T. Bookout, M.S.

Regulatory Affairs Manager, Monsanto Company

cc:

Mr. Mike Mendelsohn, EPA BPPD

Dr. Alan Reynolds, EPA BPPD

Dr. Russell P. Schneider, Monsanto Company

Mr. Daniel J. Jenkins, Monsanto Company



### TRANSMITTAL DOCUMENT

### SUBMITTED BY

Monsanto Company 800 N. Lindbergh Blvd. St. Louis, MO 63167

## REGULATORY ACTION IN SUPPORT OF WHICH THIS DOCUMENT IS SUBMITTED

Monsanto and Monsanto Licensee SmartStax® RIB Manufacturing Standard Operating Procedures

EPA File Symbol 524-LOL

TRANSMITTAL DATE

March 21, 2011

MONSANTO REFERENCE No.

07-CR-192E-E3

#### LIST OF SUBMITTED DOCUMENTS

### Administrative Materials

Administrative Materials for Monsanto and Monsanto Licensee SmartStax® RIB Manufacturing Standard Operating Procedures

MRID Number Acomposition of the

### Additional Information

Monsanto and Monsanto Licensee SmartStax® RIB Manufacturing Standard Operating Procedures

MRID Number Reject (01)

Company Official:

Jeffrey Z. Bookout, M.S.

Regulatory Affairs Manager

(314) 694-6425

Company Name:

Monsanto Company

Company Contact: Russell P. Schneider, Ph.D.

Senior Director, Regulatory Affairs and Policy

Washington D.C. (202) 383-2866



MONSANTO COMPANY 800 N. LINDBERGH BLVD. ST. LOUIS, MISSOURI 63167 http://www.monsanto.com

March 21, 2011

Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attn:

Dr. Sheryl Reilly, Branch Chief, Microbial Pesticides Branch, Biopesticide and

Pollution Prevention Division (7511P)

Subject:

Monsanto and Monsanto Licensee SmartStax® RIB Manufacturing Standard

Operating Procedures; EPA File Symbol 524-LOL

### Dear Dr. Reilly:

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Documents accompanying this letter:

Document	Category
Cover letter	Α
Transmittal document	Α
Administrative Materials for Monsanto and Monsanto Licensee SmartStax® RIB Manufacturing Standard Operating Procedures	A
Monsanto and Monsanto Licensee SmartStax® RIB Manufacturing Standard Operating Procedures	В

If you have any questions regarding this submission, please do not hesitate to contact Dr. Russell P. Schneider at 202-383-2866 or myself at 314-694-6425.

Sincerely,

Jeffrey T. Bookout, M.S.

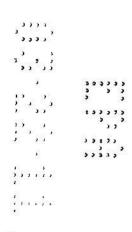
Regulatory Affairs Manager, Monsanto Company

cc: Mr. Mike Mendelsohn, EPA BPPD

Dr. Alan Reynolds, EPA BPPD

Dr. Russell P. Schneider, Monsanto Company

Mr. Daniel J. Jenkins, Monsanto Company





### TRANSMITTAL DOCUMENT

### SUBMITTED BY

Monsanto Company 800 N. Lindbergh Blvd. St. Louis, MO 63167

## REGULATORY ACTION IN SUPPORT OF WHICH THIS DOCUMENT IS SUBMITTED

Monsanto and Monsanto Licensee SmartStax® RIB Manufacturing Standard Operating Procedures

EPA File Symbol 524-LOL

### TRANSMITTAL DATE

March 21, 2011

### MONSANTO REFERENCE No.

07-CR-192E-E3

1

### LIST OF SUBMITTED DOCUMENTS

### **Administrative Materials**

Administrative Materials for Monsanto and Monsanto Licensee SmartStax® RIB Manufacturing Standard Operating Procedures

MRID Number Administrative

### Additional Information

Monsanto and Monsanto Licensee SmartStax® RIB Manufacturing Standard Operating Procedures

MRID Number Reject (01)

Company Official:

Jeffrey Z. Bookout, M.S.

Regulatory Affairs Manager

(314) 694-6425

Company Name:

Monsanto Company

Company Contact: Russell P. Schneider, Ph.D.

Senior Director, Regulatory Affairs and Policy

Washington D.C. (202) 383-2866

1



## Monsanto and Monsanto Licensee SmartStax® RIB Manufacturing Standard Operating Procedures

SmartStax® EPA File Symbol 524-LOL

#### OPP Identifier Registration United States Number Environmental Protection Agency Amendment Washington, DC 20460 Other Application for Pesticide - Section I Company/Product Number 2. EPA Product Manager 3. Proposed Classification EPA File Symbol 524-LOL Sheryl Reilly None N Company/Product (Name) Restricted 92 MON 89034 × TC1507 × MON 88017 × DAS-59122-7 5. Name and Address of Applicant (Include ZIP Code) Expedited Review. In accordance with FIFRA Section 3(c)(3)(B)(i). Monsanto Company my product is similar or identical in composition and labeling to: 800 N. Lindbergh Blvd. EPA Reg. No. St. Louis, MO 63167 Product Name Check if this is a new address Section - II Final printed labels in response to Amendment - Explain below. Agency letter dated Resubmission in response to Agency letter dated "Me Too" Application. Other - Explain below. Notification - Explain below. Explanation: Use additional page(s) if necessary. (For Section I and Section II.) Monsanto and Monsanto Licensee SmartStax® RIB Manufacturing Standard Operating Procedures Section - III 1. Material This Product Will Be Packaged In: 2. Type of Container Water Soluble Packaging Child-Resistant Packaging Unit Packaging Metal Yes\* Yes Yes Plastic No No No Glass Certification must If "Yes" No. per. If "Yes" No. per Paper Container Unit Packaging Container Package wot. be submitted Other wgt. (Specify) 5. Location of Label Directions 4. Size(s) Retail Container 3. Location of Net Contents Information On Label Label Container On Labeling accompanying product Lithograph Other 6. Manner in Which Label is Affixed to Product Paper glued Stenciled Section - IV 1. Contact Point (Complete items directly below for identification of individual to be confacted, if necessary, to process this application.) Name Telephone No. (Include Area Senior Director, Regulatory Affairs and Code) Dr. Russell P. Schneider (202) 383-2866 Policy Certification 6. Date Application I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. Received I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under epplicable law. (Stamped) 3. Title 2. Signature Regulatory Affairs Manager at J Taxl 5. Oate Jeffrey T. Bookout Tel. (314) 694-6425 March 21, 2011 Please read Instructions on reverse before completing form. Form Approved, OMB No. 2070-0060. Approval Expires 2-28-95 EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

Monsanto Company

07-CR-192E-E3

Page 2 of 5

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Applicant's/Registrant's Name, Address, and Telephone Number: (3	14) 694-6425	EPA Registration Number / File Symbol:				
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis,	MO 63167	524-LOL				
Active Ingredient(s) and/or representative test compound(s): Bacilli Cry2Ab2, CryIF, Cry3Bb1, Cry34/35Ab1 Proteins and the Genet ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary MON 89034 × TC1507 × MON 88017 × DAS-	Date: March 21, 2011					
General Use Pattem(s) (list all those claimed for this product using 40	CFR Part 158:	Product Name: MON 89034 × TC1507 ×				
Terrestrial field crop		MON 88017 × DAS-59122-7				
NOTE: If your product is a t00% repackaging of another purchase need to submit this form. You must submit the Formutator's Exemption						
I am responding to a Data-Catl-in Notice, and have included v should be used for this purpose).	vilh this form a list of companie	es sent offers of compensation (the Data Matrix form				
Section I: METHOD OF DATA	SUPPORT (Check	one method only)				
I am using the cite-all method of support, and have included very this form a list of companies sent offers of compensation (the Data Matrix Form should be used for this purpose).	the setective n	selective method of support (or cite-all option under nethod), and have included with this form a of data requirements (the Oata Matrix form must be				
Section II: GENERAL OFFER TO PAY						
[Required if using the cite-all method or when using the cite-all	ll option under the selective m	ethod to satisfy one or more data requirements)				
I hereby offer and agree to pay compensation, to other person		of this application, to the extent required by FtFRA.				
Section III: CERTIFICATION  t certify that this application for registralion, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in						
the application for registration, the form for registration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section t, this application is supported by all data in the Agency's files that (t) concern the properties or effects of this product or an identical or substantially similar product, one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.						
t certify that for each exclusive use study cited in support of this registre the written permission of the original data submitter to cite that sludy.	ation or reregistration, that I ar	n the original data submitter or that I have obtained				
I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) t am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(t)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, If any, to be paid for the use of the study.						
I certify that in all instances where an offer of compensation is require accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are avasuch evidence to the Agency upon request, I understand that the Agenconformity with FIFRA.	ilable and wilt be submitted to	the Agency upon request. Should I fail to produce				
t certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false of misleading statement may be punishable by fine or imprisonment of both under the applicable taw.						
Signature	Oate	Typed or Printed Name and Title				
March 21, 2011 Jeffrey T. Bookout, M.S. Regulatory Affairs Manager						

Monsanto Company

07-CR-192E-E3

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### **SEPA**

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

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	n, DC 20460. Do not send the form to this address.	TA MATRIX			
Date: March 21, 2011			Te	PA Reg. No./File Symbol: 524-L	OL Page Loft
Applicant's/Registrant's Name & Address:			Product: MON 89034 × TC1507 × MON 880 × DAS-59122-7		
	nsis Cryt A. 105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35At r Production in MON 89034 × TC1507 × MON 88017 ×				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Administrative Materials for Monsanto and Monsanto Licensee SmartStax® RIB Manufacturing Standard Operating Procedures.		Monsanto Compa	iny OWN	This Application
	Monsanto and Monsanto Licensee SmartStax® RIB Manufacturing Standard Operating Procedures.		Monsanto Compa	ny OWN	Manufacturing Information
Signature  Signature	and and a second		Name and Title Jeffrey T. Bookout, M. Regulatory Affairs Ma	•	

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### **SEPA**

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Applicant's/Registrant's Name & Address: Proc			EPA Reg	No./File Symbol: 524-I	OL Page t of 1
				Product: MON 89034 × TC1507 × MON 8801' × DAS-59122-7	
	sis Cryt A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35 Production in MON 89034 × TC1507 × MON 88017				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	This Application
			Monsanto Company	OWN	Manufacturing Information
Signature	Buller		Name and Title Jeffrey T. Bookout, M.S. Regulatory Affairs Manager	Date March 21, 2011	

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### Pages 292-325

\*Access to FIFRA health and safety data is restricted under FIFRA section 10(g)\*



March 18, 2011

Document Processing Desk Office of Pesticide Programs (7504P) U.S. Environmental Protection Agency Room S-4900, One Potomac Yard 2777 South Crystal Drive Arlington, VA 22202-4501 MONSANTO COMPANY
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PHONE (202) 383-2866
FAX (202) 789-1748
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Attn:

Dr. Sheryl Reilly, Branch Chief, Microbial Pesticides Branch, Biopesticide and

Pollution Prevention Division (7511P)

Subject:

Dow AgroSciences' and Monsanto's Response to Uncertainties Raised by the Scientific Advisory Panel, Dec 8-9, 2010 Regarding SmartStax® RIB; EPA File Symbol 524-LOL (Monsanto); EPA File Symbol 68467-RA (Dow AgroSciences)

### Dear Dr. Reilly:

Thank you and your team for the opportunity to review our additional modeling results, presenting worst-case seed mix effects on heterozygous fitness, relative to a 5% seed mix refuge for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 on March 15, 2011. Accompanying this letter is a document reviewing the conservative modeling results discussed in the March 15, 2011 meeting, as well as our response to the December 8-9, 2010 Scientific Advisory Panel's concerns.

The documents accompanying this letter have been classified "A" or "B", as defined by the Agency:

- Category "A": Materials that can be released to anyone, regardless of affiliation to a foreign or multi-national pesticide producer.
- Category "B": Information can be released only to individuals that attest they are not employees or agents of a foreign or multi-national pesticide producer, as per FIFRA Section 10(g).

Documents accompanying this letter:

Document	Category
Cover letter	A
Transmittal document	A
Administrative Materials for Dow AgroSciences' and Monsanto's Response to Uncertainties Raised by the SmartStax® RIB Scientific Advisory Panel, Dec 8-9, 2010	A
Dow AgroSciences' and Monsanto's Response to Uncertainties Raised by the SmartStax <sup>®</sup> RIB Scientific Advisory Panel, Dec 8-9, 2010	В

If you have any questions regarding this submission, please do not hesitate to contact Dr. Russell P. Schneider at 202-383-2866 or myself at 314-694-6514.

Sincerely,

J. Austin Burns, Ph.D.

Regulatory Affairs Manager, Monsanto Company

cc:

Mr. Mike Mendelsohn, EPA BPPD

Dr. Alan Reynolds, EPA BPPD

Dr. Russell P. Schneider, Monsanto Company

Dr. Nicholas Storer, Dow AgroSciences



### TRANSMITTAL DOCUMENT

### SUBMITTED BY

Monsanto Company 800 N. Lindbergh Blvd. St. Louis, MO 63167

## REGULATORY ACTION IN SUPPORT OF WHICH THIS DOCUMENT IS SUBMITTED

Dow AgroSciences' and Monsanto's Response to Uncertainties Raised by the SmartStax® RIB Scientific Advisory Panel, Dec 8-9, 2010

EPA File Symbol 524-LOL

### TRANSMITTAL DATE

March 18, 2011

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07-CR-192E-E2

Monsanto Company 07-CR-192E-E2 Page 1 of 2

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### LIST OF SUBMITTED DOCUMENTS

### **Administrative Materials**

Administrative Materials for Dow AgroSciences' and Monsanto's Response to Uncertainties Raised by the SmartStax® RIB Scientific Advisory Panel, Dec 8-9, 2010

MRID Number			

### Additional Information

Dow AgroSciences' and Monsanto's Response to Uncertainties Raised by the SmartStax® RIB Scientific Advisory Panel, Dec 8-9, 2010

<b>MRID</b>	Number	48423401	

Company Official:

J. Austin Burns, Ph.D.

Regulatory Affairs Manager

(314) 694-6514

Company Name:

Monsanto Company

Company Contact: Russell P. Schneider, Ph.D.

Senior Director, Regulatory Affairs and Policy

Washington D.C. (202) 383-2866



# Administrative Materials for Dow AgroSciences' and Monsanto's Response to Uncertainties Raised by the SmartStax® RIB Scientific Advisory Panel, Dec 8-9, 2010

SmartStax® EPA File Symbol 524-LOL